

DOCKET NO: S1383.70006US00

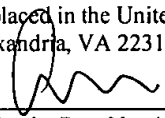
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Richard S. Blumberg et al.
Serial No: 10/215,298
Confirmation No: 5869
Filed: August 8, 2002
For: RECEPTOR SPECIFIC TRANSEPITHELIAL
TRANSPORT OF THERAPEUTICS

Examiner: David A. Saunders
Art Unit: 1644

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 13th day of May, 2004.



Alan W. Steele, Reg. No. 45,128

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT AND RESPONSE

Sir:

This paper is filed in response to the non-final Office Action mailed November 17, 2003, (Paper No. 6) in the above-captioned application. A shortened period for response was set to expire three months from the mailing date of the Office Action. A petition for a three-month extension of time for response, up to and including May 17, 2004, is filed herewith. This response is thus timely filed.

Please amend the application as follows.

Amendment to the Specification begins on page 2.

Remarks begin on page 3.

In the Specification

Please amend the specification by substituting the following paragraph for the paragraph appearing on page 1, lines 8-13:

This is a division of U.S. Serial No. 09/122,144, filed July 24, 1998 (now ~~pending~~ U.S. Patent No. 6,485,726), which is a continuation-in-part of and claims priority to U.S. Serial No. 08/899,856, filed July 24, 1997 (now U.S. Patent No. 6,030,613), which is a continuation-in-part of U.S. Serial No. 08/578,171, filed on December 29, 1995 (abandoned), which is a continuation-in-part of U.S. Serial No. 08/374,159, filed on January 17, 1995 (now U.S. Patent No. 6,086,875).

Remarks

Claims 25-40 are pending and currently under examination. No claims are amended. No claims are canceled or added. No new subject matter is introduced.

Applicants note that the Examiner indicated on page 2 of the Office Action that amendment of 2/7/03 has been entered. Applicants request clarification.

Crossed Out Reference in Information Disclosure Statement

Applicants acknowledge that the Examiner has checked off all but one of the references cited in the Form 1449 accompanying the Information Disclosure Statement filed on October 17, 2002. Applicants request explanation as to why the Examiner crossed out the Usui reference.

Objection to the Disclosure

The Examiner indicated that he objected to the disclosure because the amendment entered at page 1, lines 8-13, fails to state the patent no. of issued application 09/122,144. By current amendment to the specification, the patent no. of issued application 09/122,144 is specified as US 6,485,726. Accordingly, Applicants respectfully request the Examiner to withdraw the objection to the disclosure.

Claim Rejection Under 35 U.S.C. § 112, first paragraph

The Examiner rejected claim 37 under 35 U.S.C. § 112, first paragraph, for alleged lack of adequate written description. Applicants respectfully disagree and request the Examiner to reconsider and withdraw the rejection for reasons set forth below.

Claim 37 specifies that the cytokine of the composition of claim 25 is an interleukin. The Examiner is of the view that only interleukins 1-18 are supported by the specification. In response, Applicants submit that the claim in question is drawn to a genus of compositions in which individual species include various interleukins. Of the twenty-seven currently known interleukins, it is submitted that interleukins 1-18 represent a substantial and representative number of species upon which a claim drawn to the genus of interleukins is fairly supported. It

is therefore submitted that the claimed invention is described in sufficient detail that one skilled in the art can reasonably conclude the Applicants had possession of the claimed invention, and further, that the written description alerts the public to the limitations of the patent, allowing others to improve on the invention without infringing. Applicants respectfully submit they have met their burden and therefore request the Examiner to reconsider and withdraw the rejection of claim 37 under 35 U.S.C. § 112, first paragraph.

Claim Rejections Under 35 U.S.C. § 102

1. The Examiner rejected claims 25-26, 28-30, 33-34, and 36-40 under 35 U.S.C. § 102(b) for alleged anticipation by von Wussow (AU 8821725) in light of Guy et al. (U.S. Pat. No. 6,126,938). For reasons presented below, Applicants respectfully disagree and request the Examiner to reconsider and withdraw the rejection of claims 25-26, 28-30, 33-34, and 36-40 under 35 U.S.C. § 102(b).

In order for a prior art reference to anticipate a claim, the reference must disclose each and every limitation of the claimed invention (Glaxo Inc. v. Novopharm Ltd., 52 F.3d 1043, 1047; 34 USPQ2d 1565, 1567 (Fed.Cir. 1995)), or, with respect to anticipation-by-inherency, in order for a claim to be inherent in the prior art a person following the prior art disclosure must invariably obtain the result set forth in the claim. (Glaxo Inc. v. Novopharm Ltd., 830 F. Supp. 871, 874; 29 USPQ2d 1126, 1128 (E.D. N.C. 1993)). Applicants respectfully submit that the cited art forming the basis for the current rejection does not meet this standard, and therefore the claims are not anticipated as alleged by the Examiner. Instant claim 25 is directed to a pharmaceutical preparation for application to an apical surface of an epithelial barrier, comprising a conjugate of an agent and an FcRn binding partner, wherein the agent is a cytokine, and a pharmaceutically acceptable carrier, wherein the preparation is formulated as a unit dosage containing the conjugate in an effective amount, and wherein the pharmaceutical preparation is an oral formulation, an aerosol formulation or a nasal formulation.

The von Wussow reference, by contrast, teaches conjugates between intact human immunoglobulin, of any class, and a cytokine, but makes no disclosure whatsoever about formulation as a unit dosage or oral, nasal, or aerosol formulation. As the Examiner points out, page 26 of von Wussow discloses pharmaceutical preparations which are limited to parenteral

formulations (viz., intramuscular, subcutaneous, and intravenous). Thus the von Wussow reference does not disclose each and every feature of the claimed invention because it fails to disclose, *inter alia*, formulation as a unit dosage and oral, nasal, or aerosol formulation of the claimed conjugate.

Furthermore, von Wussow cannot form the basis for an anticipation-by-inherency rejection because von Wussow clearly teaches that immunoglobulin of any class (i.e., IgA, IgD, IgE, IgG, or IgM, see page 4, second paragraph, of von Wussow) can be used, whereas the claimed invention is limited to conjugates including an FcRn binding partner, which do not include immunoglobulin of any class (see page 13, lines 14-28, of specification). Thus because a person following the prior art disclosure of von Wussow would not invariably obtain the result set forth in claim 25, claim 25 is not anticipated.

The Examiner seeks to rely on the teachings of Guy et al. to make the anticipation rejection on the basis of von Wussow. It is respectfully submitted that this reliance is misplaced and fails to achieve its purpose. First, the Examiner acknowledges on page 4 of the Office Action that Guy et al. post-dates the effective filing date of the instant application. Second, Guy et al. teaches concurrent or consecutive administration of an antigen to nasal mucosa and to another mucosa. There is no disclosure whatsoever in Guy et al. relating to conjugates as instantly claimed. Third, with respect to the teaching of Guy et al. that pharmaceutical preparations of non-cytokine antigen, not as a conjugate, can be diluted in PBS or physiologic saline and applied drop-wise to the nostrils, Applicants respectfully submit such teaching is irrelevant to both the conjugates of von Wussow and the claimed conjugates. It is unclear to Applicants what bearing, if any, this reference might have either to von Wussow or to the instantly claimed invention. The von Wussow reference, even when taken in light of Guy et al., does not disclose each and every feature of the claimed invention because it fails to disclose, *inter alia*, formulation as a unit dosage and oral, nasal, or aerosol formulation, of the claimed conjugate. Furthermore, practice of the von Wussow disclosure, even when taken in light of Guy et al., does not invariably obtain the result set forth in claim 25. Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the rejection of claims 25-26, 28-30, 33-34, and 36-40 under 35 U.S.C. § 102(b) for alleged anticipation by von Wussow in light of Guy et al.

2. The Examiner rejected claims 25-26, 28, 31, 34, and 36-40 under 35 U.S.C. § 102(b) for alleged anticipation by von Wussow (*supra*) in light of Guy et al. (*supra*) and Pitt et al. (U.S. Pat. No. 5,354,934). For reasons set forth below, Applicants respectfully disagree and request the Examiner to reconsider and withdraw the rejection of claims 25-26, 28-30, 33-34, and 36-40 under 35 U.S.C. § 102(b).

Applicants respectfully submit that the cited art forming the basis for the current rejection does not meet the standard for anticipation, and therefore the claims are not anticipated as alleged by the Examiner. The Examiner seeks to rely on the teachings of Guy et al. and Pitt et al. to support an anticipation rejection on the basis of von Wussow. Applicants submit that the arguments presented above with respect to the rejection of claims 25-26, 28-30, 33-34, and 36-40 under 35 U.S.C. § 102(b) for alleged anticipation by von Wussow in light of Guy et al. are pertinent here as well, and they are not reproduced for the sake of brevity. The Pitt reference teaches only that erythropoietin, by itself, not as a conjugate, can be administered as an aerosol formulation. It is unclear to Applicants what bearing, if any, this reference might have either to von Wussow or to the instantly claimed invention. The von Wussow reference, even when taken in light of Guy et al. and Pitt et al., does not disclose each and every feature of the claimed invention because it fails to disclose, *inter alia*, formulation as a unit dosage and oral, nasal, or aerosol formulation of the claimed conjugate. Furthermore, practice of the von Wussow disclosure, even when taken in light of Guy et al. and Pitt et al., does not invariably obtain the result set forth in claim 25. Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the rejection of claims 25-26, 28-30, 33-34, and 36-40 under 35 U.S.C. § 102(b) for alleged anticipation by von Wussow in light of Guy et al. and Pitt et al.

3. The Examiner rejected claims 25-30, 33-35, 37, and 39-40 under 35 U.S.C. § 102(a) or (e) for alleged anticipation by Landolfi (U.S. Pat. No. 5,349,053) in light of Guy et al. (*supra*). For reasons presented below, Applicants respectfully disagree and request the Examiner to reconsider and withdraw the rejection of claims 25-30, 33-35, 37, and 39-40 under 35 U.S.C. § 102(a) or (e).

Applicants respectfully submit that the cited art forming the basis for the current rejection does not meet the standard for anticipation (*vide supra*), and therefore the claims are not

anticipated as alleged by the Examiner. The Landolfi reference teaches fusion proteins between a constant region of immunoglobulin, of any class, and a cytokine, but makes no disclosure whatsoever about formulation as a unit dosage or oral, nasal, or aerosol formulation. As the Examiner points out, Landolfi does not specifically teach a composition for intranasal administration. Rather, column 10 of Landolfi discloses pharmaceutical preparations which are limited to parenteral formulations (viz., subcutaneous, intramuscular, and intravenous). Thus the Landolfi reference does not disclose each and every feature of the claimed invention because it fails to disclose, *inter alia*, formulation as a unit dosage and oral, nasal, or aerosol formulation of the claimed conjugate.

Furthermore, Landolfi cannot form the basis for an anticipation-by-inherency rejection because Landolfi clearly teaches that constant region of immunoglobulin of any class (i.e., IgG, IgM, IgA, IgD, or IgE, see column 1, lines 25-39, of Landolfi) can be used, whereas the claimed invention is limited to conjugates including an FcRn binding partner, which do not include immunoglobulin of any class (see page 13, lines 14-28, of specification). Thus because a person following the prior art disclosure of Landolfi would not invariably obtain the result set forth in claim 25, claim 25 is not anticipated.

The Examiner seeks to rely on the teachings of Guy et al. to support the anticipation rejection on the basis of Landolfi. As mentioned above, Guy et al. teaches concurrent or consecutive administration of an antigen to nasal mucosa and to another mucosa. There is no disclosure whatsoever in Guy et al. relating to conjugates as instantly claimed. It is unclear to Applicants what bearing, if any, this reference might have either to Landolfi or to the instantly claimed invention. The Landolfi reference, even when taken in light of Guy et al., does not disclose each and every feature of the claimed invention because it fails to disclose, *inter alia*, formulation as a unit dosage and oral, nasal, or aerosol formulation of the claimed conjugate. Furthermore, practice of the Landolfi disclosure, even when taken in light of Guy et al., does not invariably obtain the result set forth in claim 25. Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the rejection of claims 25-30, 33-35, 37, and 39-40 under 35 U.S.C. § 102(a) or (e) for alleged anticipation by Landolfi in light of Guy et al.

4. The Examiner rejected claims 25-28, 31, 34-35, 37, and 39-40 under 35 U.S.C. § 102(a) or (e) for alleged anticipation by Landolfi (*supra*) in light of Guy et al. (*supra*) and Pitt et al. (*supra*). For reasons set forth below, Applicants respectfully disagree and request the Examiner to reconsider and withdraw the rejection of claims 25-28, 31, 34-35, 37, and 39-40 under 35 U.S.C. § 102(a) or (e).

Applicants respectfully submit that the cited art forming the basis for the current rejection does not meet the standard for anticipation, and therefore the claims are not anticipated as alleged by the Examiner. The Examiner seeks to rely on the teachings of Guy et al. and Pitt et al. to support an anticipation rejection on the basis of Landolfi. Applicants submit that the arguments presented above with respect to the rejection of claims 25-30, 33-35, 37, and 39-40 under 35 U.S.C. § 102(a) or (e) for alleged anticipation by Landolfi in light of Guy et al. are pertinent here as well, and they are not reproduced for the sake of brevity. As mentioned previously, the Pitt reference teaches only that erythropoietin, by itself, not as a conjugate, can be administered as an aerosol formulation. It is unclear to Applicants what bearing, if any, this reference might have either to Landolfi or to the instantly claimed invention. The Landolfi reference, even when taken in light of Guy et al. and Pitt et al., does not disclose each and every feature of the claimed invention because it fails to disclose, *inter alia*, formulation as a unit dosage and oral, nasal, or aerosol formulation of the claimed conjugate. Furthermore, practice of the Landolfi disclosure, even when taken in light of Guy et al. and Pitt et al., does not invariably obtain the result set forth in claim 25. Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the rejection of claims 25-28, 31, 34-35, 37, and 39-40 under 35 U.S.C. § 102(a) or (e) for alleged anticipation by Landolfi in light of Guy et al. and Pitt et al.

5. The Examiner rejected claims 25-28, 33-35, 37, and 39-40 under 35 U.S.C. § 102(b) for alleged anticipation by Lauffer et al. (CA 2,045,869) in light of Guy et al. (*supra*). For reasons presented below, Applicants respectfully disagree and request the Examiner to reconsider and withdraw the rejection of claims 25-28, 33-35, 37, and 39-40 under 35 U.S.C. § 102(b).

Applicants respectfully submit that the cited art forming the basis for the current rejection does not meet the standard for anticipation, and therefore the claims are not anticipated as

alleged by the Examiner. The Lauffer et al. reference teaches fusion proteins between soluble human proteins and portions of the constant regions of heavy or light chains of various classes of immunoglobulin, but makes no disclosure whatsoever about formulation as a unit dosage or oral, nasal, or aerosol formulation. Thus the Lauffer et al. reference does not disclose each and every feature of the claimed invention because it fails to disclose, *inter alia*, formulation as a unit dosage and oral, nasal, or aerosol formulation of the claimed conjugate.

Furthermore, Lauffer et al. cannot form the basis for an anticipation-by-inherency rejection because Lauffer et al. clearly teaches that various portions of the constant regions of heavy or light chains of immunoglobulins of various classes (i.e., IgG, IgM, IgA, or IgA, see page 3, line 25, of Lauffer et al.) can be used, whereas the claimed invention is limited to conjugates including an FcRn binding partner, which do not include various portions of the constant regions of heavy or light chains of immunoglobulins of various classes (*vide supra*). Thus because a person following the prior art disclosure of Lauffer et al. would not invariably obtain the result set forth in claim 25, claim 25 is not anticipated.

The Examiner seeks to rely on the teachings of Guy et al. to support the anticipation rejection on the basis of Lauffer et al. As mentioned above, Guy et al. teaches concurrent or consecutive administration of an antigen to nasal mucosa and to another mucosa. There is no disclosure whatsoever in Guy et al. relating to conjugates as instantly claimed. It is unclear to Applicants what bearing, if any, this reference might have either to Lauffer et al. or to the instantly claimed invention. The Lauffer et al. reference, even when taken in light of Guy et al., does not disclose each and every feature of the claimed invention because it fails to disclose, *inter alia*, formulation as a unit dosage and oral, nasal, or aerosol formulation of the claimed conjugate. Furthermore, practice of the Lauffer et al. disclosure, even when taken in light of Guy et al., does not invariably obtain the result set forth in claim 25. Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the rejection of claims 25-28, 33-35, 37, and 39-40 under 35 U.S.C. § 102(b) for alleged anticipation by Lauffer et al. in light of Guy et al.

6. The Examiner rejected claims 25-28, 31, 34-35, 37, and 39-40 under 35 U.S.C. § 102(b) for alleged anticipation by Lauffer et al. (*supra*) in light of Guy et al. (*supra*) and Pitt et al.

(*supra*). For reasons set forth below, Applicants respectfully disagree and request the Examiner to reconsider and withdraw the rejection of claims 25-28, 31, 34-35, 37, and 39-40 under 35 U.S.C. § 102(b).

Applicants respectfully submit that the cited art forming the basis for the current rejection does not meet the standard for anticipation, and therefore the claims are not anticipated as alleged by the Examiner. The Examiner seeks to rely on the teachings of Guy et al. and Pitt et al. to support an anticipation rejection on the basis of Lauffer et al. Applicants submit that the arguments presented above with respect to the rejection of claims 25-28, 33-35, 37, and 39-40 under 35 U.S.C. § 102(b) for alleged anticipation by Lauffer in light of Guy et al. are pertinent here as well, and they are not reproduced for the sake of brevity. As mentioned previously, the Pitt reference teaches only that erythropoietin, by itself, not as a conjugate, can be administered as an aerosol formulation. It is unclear to Applicants what bearing, if any, this reference might have either to Lauffer et al. or to the instantly claimed invention. The Lauffer et al. reference, even when taken in light of Guy et al. and Pitt et al., does not disclose each and every feature of the claimed invention because it fails to disclose, *inter alia*, formulation as a unit dosage and oral, nasal, or aerosol formulation of the claimed conjugate. Furthermore, practice of the von Wussow disclosure, even when taken in light of Guy et al. and Pitt et al., does not invariably obtain the result set forth in claim 25. Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the rejection of claims 25-28, 31, 34-35, 37, and 39-40 under 35 U.S.C. § 102(b) for alleged anticipation by Lauffer et al. in light of Guy et al. and Pitt et al.


Summary

Amendment is made to the specification to overcome an objection to the disclosure. Arguments are advanced to address and overcome all claim rejections under 35 U.S.C. § 112, first paragraph, and 35 U.S.C. § 102(a), (b), and/or (e).

Applicants request an explanation as to why the Examiner crossed out one reference on the Form 1449 filed October 17, 2002.

Applicants believe the claims are in condition for allowance. An early and favorable action is hereby requested.

Respectfully submitted,
Richard S. Blumberg et al., Applicants

By: 

Alan W. Steele, Reg. No. 45,128
Wolf, Greenfield & Sacks, P.C.
600 Atlantic Avenue
Boston, Massachusetts 02210-2211
Telephone: (617) 720-3500

Docket No. S1383.70006US00
Date: May 13, 2004
X05/17/04X



41 16448
Docket No.: S1383.70006US00

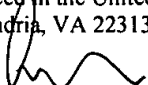
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Richard S. Blumberg et al.
Serial No: 10/215,298
Confirmation No: 5869
Filed: August 8, 2002
For: RECEPTOR SPECIFIC TRANSEPITHELIAL TRANSPORT OF
THERAPEUTICS

Examiner: David A. Saunders
Art Unit: 1644

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 13th day of May, 2004.


Alan W. Steele, Reg. No. 45,128

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Transmitted herewith are the following documents:

- ☒ [X] Amendment and Response
- ☒ [X] Petition for Three-Month Extension
- ☒ [X] Return Receipt Postcard

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 720-3500, Boston, Massachusetts.

A check in the amount of \$950.00 is enclosed. If no check is enclosed, or if a fee in a different amount is required, the Commissioner is hereby authorized to charge or credit Deposit Account No. 23/2825 the amount of the fee or the difference. A duplicate of this sheet is enclosed.

Respectfully submitted,
Richard S. Blumberg et al., Applicant

By: 

Alan W. Steele, Reg. No. 45,198
Wolf, Greenfield & Sacks, P.C.
600 Atlantic Avenue
Boston, Massachusetts 02210-2211
Telephone: (617)720-3500

Docket No. S1383.70006US00
Date: May 13, 2004
x05/17/04x

FIG. 25c is a side sectional view of three lumbar vertebrae and the chisel of FIG. 25 cutting the opposing surfaces of adjacent vertebrae.

FIG. 25d is a side sectional view of three lumbar vertebrae and the chisel of FIG. 25 after completing the initial cavity formation in the intervertebral space.

5 FIG. 26 is a perspective view of a bone shaver according to the present invention.

FIG. 26a is a perspective view of the cutting head of the bone shaver of FIG. 26.

FIG. 27 is a perspective view of one embodiment of a slap hammer for use with the present invention.

10 FIG. 28 is a perspective view of one embodiment of a nerve retractor assembly according to the present invention.

FIG. 29 is a perspective view of a retractor holder illustrated in FIG. 28.

FIG. 29a is a partial perspective view of the back of the support blade for the retractor of FIG. 29.

15 FIG. 30 is a perspective view of the retractor blade for the retractor of FIG. 29.

FIG. 30a is a partial perspective view of the lead tip of retractor blade in FIG.

30.

FIG. 31 is a perspective view of one embodiment of a distractor for use with the present invention.

20 FIG. 31a is a partial perspective view of the distractor tip of the distractor depicted in FIG. 31.

FIG. 32 is a perspective view of a round scraper for use in the present invention.

FIG. 32a is a partial perspective view of the scraper head of the round scraper depicted in FIG. 32.

25 FIG. 32b is a side view of the round scraper of FIG. 32.

FIG. 32c is an elevated top view of the round scraper of FIG. 32.

FIG. 32d is a perspective view of the scraper head of the round scraper of FIG.

32.

FIG. 32e is an elevated top view of the scraper head of the round scraper of

30 FIG. 32. FIG. 32.

FIG. 32f is a side view of the scraper head of the round scraper of FIG. 32.

FIG. 33 is a perspective view of a plane scraper for use in the present invention.

FIG. 33a is a perspective view of the scraper head of the plane scraper depicted in FIG. 33.

FIG. 33b is a side view of the plane scraper of FIG. 33.

5 FIG. 33c is an elevated top view of the plane scraper of FIG. 33.

FIG. 34 is a perspective view of a rotatable cutter for use with the present invention.

FIG. 34a is a perspective view of the cutting head of the rotatable cutter depicted in FIG. 34.

10 FIG. 34b is an elevated top view of the rotatable cutter of FIG. 34.

FIG. 34c is a side view of the rotatable cutter of FIG. 34.

FIG. 34d is a first end view of the rotatable cutter of FIG. 34.

FIG. 35 is a perspective view of a toothed scraper for use according to the present invention.

15 FIG. 35a is a perspective view of the cutting head of the toothed scraper depicted in FIG. 35.

FIG. 36 is a perspective view of one embodiment of a guide sleeve for receiving surgical instruments and implantation instruments of the present invention.

FIG. 37a is a perspective view of an alternative embodiment of a chisel for use
20 in the present invention.

FIG. 37b is an elevated top view of the chisel in FIG. 37a.

FIG. 37c is a side view of the chisel in FIG. 37a.

FIG. 38 is a side view of the chisel depicted in FIG. 37a received inside the guide sleeve depicted in FIG. 36.

25 FIG. 39a is a perspective view of an alternative embodiment of an implant holder.

FIG. 39b is an elevated top view of the implant folder depicted in FIG. 39a.

FIG. 39c is a side view of the implant holder depicted in FIG. 39a.

FIG. 39d is a cross-sectional view of the implant holder depicted in FIG. 39a.

30 FIG. 39e is an enlarged view of the gripping head of the implant holder depicted in FIG. 39a.

FIG. 39f is a perspective end view of the gripping head of the implant holder depicted in FIG. 39a.

FIG. 40a is a perspective view of an implant inserter according to the present invention.

5 FIG. 40b is an elevated top view of the implant inserter depicted in FIG. 40a.

FIG. 40c is a side view of the implant inserter depicted in FIG. 40a.

FIG. 41 is a perspective cutaway view of a bone graft loader with the piston in a first position within the loader shaft according to the present invention.

10 FIG. 42 is a perspective cutaway view of the bone graft loader of FIG. 41 with the piston in a second position within the loader shaft.

FIG. 43a is a cutaway view of an intervertebral space that includes a bone graft loader of FIG. 41 loaded with osteogenic material received within a protective sleeve and the intervertebral space.

15 FIG. 43b is a cutaway view of an intervertebral space and the implant holder of FIG. 41 delivering osteogenic material into the intervertebral space.

FIG. 44a is a top sectional view of an idealized diaphysis section of a long bone and the section needed for forming a cortical bone dowel.

20 FIG. 44b is a side view of an idealized section from the diaphysis of a long bone indicating the medullary canal and the portion of the bone needed for forming a cortical bone dowel of the prior art.

FIG. 44c is a perspective view of a cortical bone dowel formed from the diaphysis section of 44a.

FIG. 45 is an elevated top view of the remnant of the bone section from FIG. 44a.

25 FIG. 46 is a perspective view of the bone remnant from FIG. 44a.

FIG. 47 is a top sectional view of an upper portion of the diaphysis of a humeral shaft.

FIG. 48 is a top sectional view of an upper portion of the diaphysis of a tibial shaft.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

For the purposes of promoting an understanding of the principles of the present invention, reference will now be made to the embodiments illustrated in the drawings, and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is intended thereby. Any alterations and further modification in the described processes, systems, or devices, and any further applications of the principles of the invention as described herein are contemplated as would normally occur to one skilled in the art to which the invention relates.

This invention provides bone implants for insertion into the intervertebral spaces between adjacent vertebrae following discectomy. The bone implants are useful for maintaining and/or restoring a desired spacing between adjacent vertebrae. The bone implants of the present invention include a recessed area that serves as a depot for receiving osteogenic material, thereby enhancing bone ingrowth and fusion of the adjacent vertebrae. The implants of the present invention are designed to conserve donor bone material without compromising necessary biomechanical properties of the implant to support the forces generated at the implantation level. Multiple implants according to the present invention may be formed from a single donor bone. Further, the implants according to the present invention may be obtained from remnants of donor bone utilized to form alternative implants and from the upper and lower end portions of the diaphysis of long bones lacking the required properties for cylindrical dowels, collectively referred to herein as "remnants." Preferably, each implant includes at least a portion influenced by the shape of the medullary canal. Preferably, the medullary canal is included as a curved surface in the body of the implant that can serve as a depot for osteogenic material. Optimally, the design of the implant includes surface features which inhibit expulsion of the implant from the preformed cavity.

Referring now to FIG. 1 through FIG. 6, one embodiment of an implant according to the present invention is illustrated. Implant 10 includes body 11 having a concave surface 14 that defines a recessed area 15 into body 11. Implant 10 further

includes a tool attachment end 32 adapted for engagement with an implant holder. Tool attachment end 32 can include a variety of recesses, receptacles, grooves, slots, projections, and other supporting members to engage corresponding surface features on an implant holder. Implant 10 also includes an insertion end 17. On the implant
5 illustrated in FIGS. 1-6, the insertion end is defined by curved surface 18. It is understood that curved surface 18 can also include surfaces having a uniform and non-uniform curvature and tapered ends for increasing the ease of insertion of the implant into the intervertebral space.

Body 11 of implant 10 is substantially elongated and defines a longitudinal axis
10 19. The length of the implant 11 is sufficient to provide sufficient support and stability to the spinal column. Typically the implant has a length of about 21 mm to about 27 mm, more preferably, about 22 mm to about 26 mm. When viewed from the side, the height of implant 10 can be substantially uniform for its entire length, which lies parallel to the longitudinal axis. Alternatively, as illustrated in FIG. 2, the height
15 of implant 10 can vary along its length. The maximum height of implant 10 is about 11 mm to about 15 mm in height as shown by reference line 21. The lesser height 23 of implant 10 is about 7 mm to about 11 mm. The maximum width 25 of implant 10 may not exceed the width of the bone remnants, which serve as the source of donor bone for the implants. However, the implant is formed with a sufficient maximum
20 width to adequately support the forces generated at the site of implantation and to provide stability to the implant to inhibit rotation in the disc space. Furthermore, in preferred embodiments, the width of the implant is sufficient to withstand a downward applied compressional force of about 30,000 Newtons. The width of the implant is about 8 mm. to about 14 mm, more preferably about 10 mm to about 12
25 mm.

The outer surface of implant 10 can include surface features such as ridges or teeth to prevent retropulsion of the implant from the intervertebral space. Ridges 12 can be randomly or uniformly distributed about the outer surface of implant 10. The ridges 12 can be distributed on one, two, three, or four sides of the exterior surface of
30 implant 10. Preferably, ridges 12 and 13 are located on the upper surface 40 and lower surface 42, respectively. Ridges 12 and 13 are defined as an equilateral triangle

defining an angle of about 50 to about 70° at the apex and having a height of about 1 mm.

Body 11 of implant 10 includes a recessed area 15 that can be used for receiving osteogenic material. One side of implant 10 includes concave surface 14 formed as a result of the medullary canal of the long bone. While concave surface 14 generally follows the contours of the medullary canal of the donor bone, it will be understood that cleaning and preparing the bone graft from the donor may slightly alter the medullary canal, thereby altering the configuration of concave surface 14. Moreover, concave surface 14 typically resembles a portion of a cylindrical wall. However, the specific configuration of the surface may vary, depending on the shape of the medullary canal in the donor bone. Concave surface 14 defines a recessed area 15. In addition to concave surface 14, the implant can include other apertures such as apertures 20 and 22. In preferred embodiments, apertures 20 and 22 extend through implant 10 and are sized to receive a sufficient amount of an osteogenic material to promote bone ingrowth and fusion of the adjacent vertebrae.

Implant body 11 includes a substantially flat side 16 opposite concave surface 14. Flat side 16 adjoins tool engagement end 32 and extends along the length of body 11 to abut insertion end 17. It is understood for the purposes of this invention that flat side 16 is substantially planar. However, it is also within the scope of the present invention that flat side 16 can include a curved surface, if desired.

Tool attachment end 32 can include a variety of recesses, apertures, and other structural features to engage an implant holder. For example, as depicted in FIGS. 4 and 5, tool engagement end can include slots 24, 26, first indent 28 and second indent 30. First indent 28 and second indent 30 can be provided to matingly engage corresponding pins on an implant holder.

Insertion end 17, which includes rounded surface 18 is depicted in FIG. 6. It is desirable, but not necessary, that rounded end 18 defines a uniform curvature as depicted in FIG. 6. It is desirable to round over or streamline the end of implant body 10 to ease the insertion of the implant into a preformed cavity. Therefore, in addition to curved surface 18, the implant also includes incline surfaces 34 and 36. Inclined surfaces 34, 36 and curved surfaces 18 may be provided to facilitate insertion of the

implant into the preformed cavity. As explained further herein, such curved end surfaces obviate the necessity to provide a squaring off of the bottom of the channel of the preformed cavity.

It is also provided with the present invention an implant holder for releaseably securing and impacting the implant of FIGS. 1-6 into the preformed cavity. One embodiment of the implant holder is depicted in FIGS. 7 - 10. Implant holder 50 includes handle 70, gripping head 59, first branch 52 engaged to handle 70 and second branch 54. Second branch 54 is pivotally attached to first branch 52 with pivot pin 56. Gripping head 59 includes a first gripping arm 60 integral to second branch 54 and a second gripping arm 62 integral to first branch 52. Thus, in preferred embodiments gripping arm 62 remains stationary while gripping arm 60 pivots on pivot pin 56 to provide access to a recess cavity 68 formed between opposing gripping arms 60 and 62. Gripping arms 60 and 62 include projections 64 and 66, respectively. Projections 64 and 66 are adapted to matingly engage first indent 28 and second indent 30 on implant 10. Furthermore, gripping head includes a surface for contacting the tool engaging end 32 of implant 10 to drive the implant into a preformed cavity. In the preferred embodiment illustrated in FIGS. 7-10, gripping arms 60 and 62 include impacting surfaces 61 and 63, respectively. Impacting surface 61 abuts and is substantially orthogonal to the interior side of gripping arm 60. Impacting surface 63 is similarly disposed on gripping arm 62.

Opposite end of gripping arms 60 and 62 are first branch 52 and a second branch 54, respectively. First branch 52 is connected to handle 70 and remains stationary along with gripping arm 62. However, second branch 54 on the opposite end of gripping arm 60 opens by pivoting on pivot pin 56. Pivoting of branch 54 on pivot pin 56 causes gripping arm 60 to move away from gripping arm 62 and, thus, open the recessed cavity 68 to receive tool engaging end 32 of implant 10. After receiving tool engaging end 32, second branch 54 is then pivoted towards first branch 52 to close recess cavity 68 and securely engage the projection 64 and 66 into first and second attachment recesses 24 and 26 and first and second indents 28 and 30 on implant 10.

Once branching arm 54 abuts or nearly abuts branching arm 52, locking pin 58 engages first branch 52 and prevents pivoting of second branch 54. Implant 10 can be released from implant holder 50 by disengaging locking pin 58 and pivotally opening second branch 54 from first branch 52. Alternatively, other locking means such as a
5 slidable sleeve or a collet that are adapted to encircle first and second branches and prevent opening of the gripping arms can be used with the present invention. While locking pin 58 is illustrated in FIGS. 8-10 as one embodiment of securely engaging implant 10, it is contemplated that other locking means or mechanisms known to
those skilled in the art can be used with the present invention.

10 Implant holder 50 engaged to implant 10 can be used to insert the implant into the intervertebral space as depicted in FIG. 11. Insertion tube 90 is inserted into disc space 82 in a far lateral PLIF approach that can be used with a transforaminal procedure. Implant 10a is depicted as fully seated in a first preformed cavity adjacent to vertebral body 80. In a preferred embodiment, insertion tube 90 is first positioned
15 adjacent the preformed cavity. Insertion tube 90 is adapted to slidably receive implant 10 and implant holder 50. After implant 10 is securely engaged in the preformed cavity, locking pin 58 is released, thereby allowing second branch 54 to pivot away from first branch 52 and release engagement of projections 64, 66, and gripping arms 60 and 62 from the corresponding attachment recesses and indents on implant 10.
20 Insertion tube 90 may be sized to permit movement of the branches therein or may be withdrawn to allow sufficient movement for disengagement. Implant holder 50 and insertion tube 90 are then removed.

In FIG 11a a "J" shaped implant and an implant holder disposed within the disc space is illustrated. A first implant 210a is depicted as fully seated in the disc space
25 82. Insertion tube 90 provides access to the disc space 82 from the posterior side of the vertebral body 80 for insertion of implant 210. Recessed areas 219 on implants 210 and 210a are disposed medially.

An alternative embodiment of an implant prepared according to the present invention is depicted in FIGS. 12-16. Implant 110 is formed in elongated J-shaped
30 body 111 that defines a longitudinal axis 119. One side of J-shaped body 111 includes curved section 122 that adjoins J-end 128 to form the crook of the J-shape

and is bounded by straight section 120 opposite J-end 128. In a preferred embodiment, curved section 122 includes internal concave surface 114. Preferably, concave surface 114 is contoured based on the medullary canal of a long bone. Straight section 120 abuts tool attachment end 132. Tool attachment end 132 includes tool engagement recess 124 for securely engaging an implant holder. Tool engagement recess 124 is adapted to secure implant 110 in the implant holder to minimize vertical movement of the implant while the implant is being inserted into preformed cavity. It is contemplated that the tool engagement end 132 can further include a variety of tool engagement structures, such as grooves, receptacles, holes, recesses, projections, pins, and detents. Upper tool recess 126 is disposed between tool engagement end 132 and flat side 116. Flat side 116, which is opposite straight section 120, defines the back or laterally disposed portion of J-shaped body 111 and abuts insertion end 117 on one end and on the opposite end abuts shoulder 127. Insertion end 117 includes curved surface 118. While not specifically illustrated in FIGS. 12-16, implant 11 is provided to have a length, height and width as described for implant 10.

A plurality of ridges 112 and 113 are provided on the top surface 129 and bottom surface 130 of implant 110. It is more or less depicted that top surface 129 and bottom surface 130 include a series of ridges 112 and 113. However, it is contemplated that ridges can be defined on one, two, three or four sides of implant 110.

An alternative preferred embodiment of an implant holder is illustrated in FIGS. 17-21. Implant holder 150 includes a shaft 151 that defines a longitudinal axis 164. The shaft 151 includes gripping head 152 on one end and coupling point 153 on the opposite end. The shaft splits into an upper branch 154 and a lower branch 156. The upper and lower branches are separated by channel 158. Upper branch 154 includes upper branch extension 160, and lower branch 156 includes lower branch extension 170. Collectively upper branch extension and lower branch extension define the gripping head 152.

The gripping head 152 includes at least one implant engaging structure. Preferably gripping head includes projections 166 and 168 that engage in

corresponding recesses in the implant. The projections are provided to control lateral and vertical motion as the implant is impacted into the intervertebral space.

Optimally, gripping head also includes a surface that can be used to impact or drive the implant in the preformed cavity.

5 In preferred embodiments, the gripping head illustrated in FIGS. 17-21 includes upper and lower branch extensions 160 and 170, respectively. Upper branch extension 160 includes incline surface 162, which is provided to matingly engage straight section 120 on implant 110. Branch extension 160 includes tapered end 166 that matingly engaging tool engagement recess 124. Lower branch extension 170
10 includes end 172 for engaging shoulder 127 on implant 110. Furthermore, lower branch extension 170 includes tapered end 168, which along with tapered end 166, is provided for engaging tool engagement recess 124. Tapered ends 166 and 168 engage in tool recess 124 to prevent lateral movement of the implant during impacting to force the implant into the preformed cavity.

15 As shown in FIG. 19, the shaft also includes outer sleeve 184, which is moveable along the shaft in a direction parallel to the longitudinal axis and urges the upper and lower branches together when the outer sleeve 184 is moved in the direction toward gripping head 152. Movement of outer sleeve 184 is controlled by the threaded engagement of threaded nut 182 with external threads 157. Outer sleeve
20 184 includes an internal surface (not shown) adapted to engage inclined surfaces 155 and 159 on the inner shaft to urge the branches together.

 Moving outer sleeve 184 on shaft 151 toward the gripping head urges upper and lower branches 154 and 156 and upper and lower branch extensions 160 and 170 toward each other. Thus, upper and lower branches clamp and secure an implant in
25 the gripping head.

 Coupling point 153 is included on shaft 151 opposite from gripping head 152. Coupling point 153 is used to attach a handle 180 or an impacting tool to drive an included implant in to preformed cavity.

 In FIGS. 19-21, implant 110 is depicted mounted in implant holder 150. Upper
30 and lower branch extensions 160 and 170 clamp implant in gripping head 152. FIG. 20a and 21 illustrate the implant engaged in an implant holder. The implant is

positioned to lie inside the lateral edges of the vertebral body. The concave area is positioned to face medially. A second implant may be positioned on the opposite side of the vertebral body. The concave areas of the two implants would face each other to form a enclosed area to serve as a depot for osteogenic material.

5 Yet another embodiment of an implant according to the present invention is depicted in FIG. 22. Implant 210 includes crescent-shaped body 211 having a convex surface 217 and an opposite concave surface 215. Convex surface 217 is disposed between tool-engaging end 222 and opposite insertion end 216. Implant 210 is depicted as having a series of ridges 212 projecting out of upper surface 214 and
10 similar ridges 213 projecting from the lower surface for engaging bone surfaces. It is understood that implant 210 can be prepared having a fewer number of ridges than depicted in FIG. 22. For example, implant 210 can include surfaces having no ridges, or ridges on one, two, three, or four or more surfaces. Implant 210 is provided with a length, height and width as is generally described for implant 10.

15 Concave surface 215 adjoins abutting surface wall 226 and on opposite end adjoins taper surface 220. While concave surface 215 gradually follows the contours of the medullary canal, it is understood that cleaning and machining the bone graft from a donor may slightly alter the medullary canal, thereby altering the configuration of concave surface 215. Preferably, a portion of concave surface 215 is formed from
20 a section of the medullary canal of a long bone. Concave surface 215 defines a recessed area 219 that serves as a depot for osteogenic material.

Insertion end 216 is provided to increase the ease of insertion of the implant into a preformed cavity. Thus, it is within the scope of this invention to provide insertion end 216 having a substantially streamlined shape. For example, insertion end 216 can
25 include a bullet-shape, a curved shape, a frustoconical shape and/or a conical shape. In the preferred embodiment illustrated in FIG. 22, insertion end 216 is bounded on three sides by tapered surfaces 218, 220 and 221. While not specifically illustrated in FIG. 22, insertion end 216 also can be bounded by a fourth tapered surface opposite tapered surface 220. Alternatively, opposite tapered surface 220, insertion end 216
30 can abut convex surface 217.

Tool engaging end 222 is opposite of insertion end 216 on crescent shaped body 211. As with other preferred embodiments of the implants for use with the present invention, tool engaging end can include a variety of recesses, receptacles, grooves, slots, projections, and other supporting members to engage corresponding surface features on an implant holder. In the preferred embodiment illustrated in FIG. 22, tool engaging end 222 includes central opening 224. Central opening 224 is provided for slidably receiving a pin or a rod extension on an implant holder. Preferably central opening 224 is provided with internal threads for threadedly engaging a threaded pin or rod extension on an implant holder. Central opening 224 can extend over about 50% through body 211, more preferably central opening extends greater than about 80% through body 211. Most preferably, central opening 224 extends through body 211 of implant 210 so that an inserted pin or rod extension extends through or to insertion surface 216. In preferred embodiments, central opening 224 contains a uniform cross-sectional area throughout. It is understood that central opening 224 can include segments with different diameters and/or taper from tool engaging end to insertion end 216 to receive a pin or rod extension of an implant holder that has the corresponding segment(s) or taper. (See, for example, the rod extension 246 in Fig. 32a). It is depicted in FIG. 22 that central opening 224 extends through the recessed area 219 defined by concave surface 215; however, it is understood that alternative embodiments of implant 210 may provide a central opening 224 that extends through or part way through implant 210 without accessing the recessed area 219.

Yet another embodiment of an implant holder is depicted in FIGS. 23-24. Implant holder 240 includes extension 243, handle 241, shaft 242, and gripping head 244. Shaft 242 defines a longitudinal axis 247. Gripping head 244 includes a first surface 250 for abutting and impacting the tool engaging end 222 to drive implant 210 into a prepared cavity. Thus, the implant holder not only releaseably secures an implant, but also provides a means for impacting the implant into a preformed cavity. Preferably, first surface 250 is roughened to better secure engaged implant 210. Gripping head 244 also includes a holder extension 248 adjoining first surface 250 at corner 252 at an included angle 253 of about 90°, preferably orthogonal to the

direction of impaction or insertion. However, in alternative embodiments, holder extension 248 can abut the first surface 250 and form an included obtuse angle 253 between the first surface and the holder extension. Alternatively, the holder extension 248 can abut the first surface 250 and form an acute included angle 253 between the first surface and the holder extension. (See, for example, similar structure inclined surface 162 in FIG. 17a). It is understood that the angle between the first surface and holder extension 248 can be provided to frictional secure abutting surface 226 and tool engaging end 222 on implant 210. Thus, holder extension 248 can be adapted to inhibit lateral movement of the implant as it is impacted in the cavity.

Gripping head 244 also includes first rod extension 246. First rod extension 246 can include external threads for engaging internal threads in a tool receiving recess in an implant. Preferably rod extension 246 is radiopaque to provide an X-ray indicator of the location of the implant during surgery. Extension rod 246 can be fixedly mounted onto first surface 240. Alternatively, shaft 242 disposed between gripping head 244 and handle 241 can be, but is not required to be, hollow for receiving holder extension 248. Extension rod 246 can extend through an aperture (not shown) on surface 244 to be received within shaft 242. In yet another alternative embodiment, first surface 250 can include a second rod extension 245. Second Rod extension 245 is adapted to receive first extension rod 246 therein so extension rod 246 is in communication with shaft 242.

Shaft 242 can include extension 243 for extending extension rod 246 through first surface 250. For example, the end of extension rod received within shaft 242 can include external threads that engage internal threads of extender 243. Twisting extender 243 caused extension rod to travel in a longitudinal direction parallel to the longitudinal axis 247 through shaft 242.

When the implants described in this present invention are inserted into a intervertebral space, the recessed areas defined by curved surfaces on the implants and the adjoining surfaces of the adjacent vertebra form a chamber or depot for osteogenic material. (See FIG. 11).

The recessed areas defined by curved surfaces of the implants described in the present invention can be packed with any suitable osteogenic material. The implants

can be packed with osteogenic material prior to implantation or the osteogenic material may be inserted in to the chamber or depot in the intervertebral space after one or two of the implants have been inserted. In a preferred embodiment, the osteogenic composition substantially fills the recessed areas defined by the implants so that the osteogenic composition will contact the endplates of the adjacent vertebrae when the implant is implanted within the vertebrae. When "spongy" osteogenic material such as cancellous bone tissue is used, the cancellous tissue can be compressed into the recessed area or chamber to insure sufficient contact with adjacent endplates. This provides better contact of the composition with the endplates to stimulate bone ingrowth.

Any suitable osteogenic material or composition is contemplated, including autograft, allograft, xenograft, demineralized bone, and synthetic and natural bone graft substitutes, such as bioceramics and polymers, and osteoinductive factors. The terms osteogenic material or osteogenic composition used herein broadly include any material that promotes bone growth or healing including autograft, allograft, xenograft, bone graft substitutes and natural, synthetic and recombinant proteins, hormones and the like.

Autograft can be harvested from locations such as the iliac crest using drills, gouges, curettes and trephines and other tools and methods which are well known to surgeons in this field. Preferably, autograft is harvested from the iliac crest with a minimally invasive donor surgery. The osteogenic material may also include bone reamed away by the surgeon while preparing the end plates for the spacer.

Advantageously, where autograft is chosen as the osteogenic material, only a small amount of bone material is needed to pack the chamber. The autograft itself is not required to provide structural support as this is provided by the spacer. The donor surgery for such a small amount of bone is less invasive and better tolerated by the patient. There is usually little need for muscle dissection in obtaining such small amounts of bone. The present invention therefore eliminates or minimizes many of the disadvantages of employing autograft to provide structural support in the fusion procedure.

Natural and synthetic graft substitutes which replace the structure or function of bone are also contemplated for the osteogenic composition. Any such graft substitute is contemplated, including for example, demineralized bone matrix, mineral compositions and bioceramics. As is evident from a review of *An Introduction to Bioceramics*, edited by Larry L. Hench and June Wilson (World Scientific Publishing Co. Ptd. Ltd., 1993, volume 1), there is a vast array of bioceramic materials, including BIOGLASS®, hydroxyapatite, and calcium phosphate compositions known in the art which can be used to advantage for this purpose. That disclosure is herein incorporated by reference for this purpose. Preferred calcium compositions include bioactive glasses, tricalcium phosphates, and hydroxyapatites. In one embodiment, the graft substitute is a biphasic calcium phosphate ceramic including tricalcium phosphate and hydroxyapatite.

In some embodiments, the osteogenic compositions used in this invention comprise a therapeutically effective amount to stimulate or induce bone growth of a bone inductive or growth factor or protein in a pharmaceutically acceptable carrier. The preferred osteoinductive factors are the recombinant human bone morphogenetic proteins (rhBMPs) because they are readily available and do not contribute to the spread of infectious diseases. Most preferably, the bone morphogenetic protein is a rhBMP-2, rhBMP-4 or heterodimers thereof.

Recombinant BMP-2 can be used at a concentration of about 0.4 mg/ml to about 1.5 mg/ml, preferably near 1.5 mg/ml. However, any bone morphogenetic protein is contemplated including bone morphogenetic proteins designated as BMP-1 through BPM-13. BMPs are available from Genetics Institute, Inc., Cambridge, Massachusetts, and may also be prepared by one skilled in the art as described in U.S. Patent Nos. 5,187,076 to Wozney et al.; 5,366,875 to Wozney et al.; 4,877,864 to Wang et al.; 5,108,922 to Wang et al.; 5,116,738 to Wang et al.; 5,013,649 to Wang et al.; 5,106,748 to Wozney et al.; and PCT Patent Nos. WO93/00432 to Wozney et al.; WO94/26893 to Celeste et al.; and WO94/26892 to Celeste et al. All osteoinductive factors are contemplated whether obtained as above or isolated from bone. Methods for isolating bone morphogenetic protein from bone are described in U.S. Patent No. 4,294,753 to Urist and Urist et al., 81 PNAS 371, 1984.

The choice of carrier material for the osteogenic composition is based on biocompatibility, biodegradability, mechanical properties and interface properties as well as the structure of the load-bearing member. The particular application of the compositions of the invention will define the appropriate formulation. Potential carriers include calcium sulphates, polyactic acids, polyanhydrides, collagen, calcium phosphates, polymeric acrylic esters and demineralized bone. The carrier may be any suitable carrier capable of delivering the proteins. Most preferably, the carrier is capable of being eventually resorbed into the body. One preferred carrier is an absorbable collagen sponge marketed by Integra LifeSciences Corporation under the trade name Helistat® Absorbable Collagen Hemostatic Agent. Another preferred carrier is a biphasic calcium phosphate ceramic. Ceramic blocks are commercially available from Sofamor Danek Group, B.P. 4-62180 Rang-du-Fliers, France and Bioland, 132 Route d'Espangne, 31100 Toulouse, France. The osteoinductive factor is introduced into the carrier in any suitable manner. For example, the carrier may be soaked in a solution containing the factor. One preferred embodiment contemplates use of OSTEOFIL® allograft paste sold by Regeneration Technologies, Inc. The allograft paste can be supplemented with a local autograft obtained from the cutting operation.

The present invention also includes instrumentation for preparing the intervertebral space between adjacent vertebrae for receiving an implant and for inserting the implant into the prepared space. Use of the implants in accordance with the present invention restores the disc height, restores segmental alignment and balance, protects nerve roots, restores weight bearing to anterior surfaces, and immobilizes the unstable degenerated intervertebral disc area. The spacers of this present invention may be conveniently implanted with known instruments and tools although improved instruments are provided that are specifically adapted for the procedure. Any instrument that will firmly hold the implant and permit the implant to be inserted is contemplated. Preferably, the instrument will be adapted to compensate for the open structure of the spacers of this invention.

It is also provided with the present invention instruments for using and inserting the implants described herein. Specific instruments include box chisels, impact or

slap hammers, shavers, retractors, detractors, scrapers such as round scrapers, plain scrapers, rotatable scrapers or cutters, toothed scrapers and bone loaders. In addition, there is provided a protective sleeve illustrated in FIG. 36 for use in guided surgical procedures.

5 In one aspect of the invention, a novel chisel is provided. The novel chisel for preparation of the preformed cavity in the intervertebral disc space is depicted in FIGS. 25 through 25d. Box chisel 260 includes a handle 262, having an engagement hole 263 adapted for attachment of an impacting tool such as a slap hammer shown in FIG. 27. In addition, box chisel 260 includes shaft 264 extending from handle 262
10 and connecting with cutting head 266. Shaft 264 defines a longitudinal axis 261. Cutting head 266 includes first arm 267 and opposing second arm 269 extending from shaft 264 substantially parallel to longitudinal axis 261. Upper cutting blade 268 and opposing lower cutting blade 270 are disposed between first and second arms 267 and 269. First arm 267 and second arm 269 define internal cavity 276 for receipt of bone
15 chips and cutting debris. One or both of first arm 267 and second arm 269 include index markings 274, which indicate the depth of cut for the box chisel, thus allowing the surgeon to determine how deeply he/she has cut into the intervertebral space.

Non-cutting edge 273 is attached to first arm 267. Similarly, non-cutting edge 272 is attached to first arm 269. Non-cutting edges 273 and 272 are positioned to
20 extend distally beyond cutting blades 268 and 270 in a direction parallel to the longitudinal axis. Referring to FIG. 25b-c, non-cutting edge 273 includes an upper guide portion 296 and a lower guide portion 298 extending at least partially beyond the cutting edges. Similarly, non-cutting edge 272 includes identical upper and lower guiding portions. The guiding portions contact the surface prior to the cutting edges
25 268 and 269. Preferably the non-cutting edges 273 and 272 of the adjacent vertebrae are rounded to follow the interior surfaces of the opposing end plates of adjacent vertebrae. Thus, the rounded non-cutting edges follow along the surfaces of end plates and center the box cutter within the disc space and the included upper and lower cutting blades 268 and 270 between the two end plates. When the two cutting
30 blades are centered between the opposing endplates, the blades cut equal amounts of bone from each end plate and are prevented from creating a potential offset opening

- between the endplates, resulting in improper implant placement and excess bone removal, which could increase the risk of implant interface subsidence.

Attachment hole 263 in handle 262 of box chisel 260 is provided for attachment of an impact or slap hammer as depicted in FIG. 27. Impact hammers are well known in the art and attachment hole 263 can be provided for attachment to any of the known impact hammers for use with the present invention. In preferred embodiments, slap hammer 310 includes threaded end 320. Threaded end 320 is threadedly engaged in internal threads in 263. Slap hammer 310 includes weight 316 that slides on shaft 314. Use of a slap hammer in accordance with this invention allows for controlled force impacting cutting tool and implants. The slap hammer also provides a means for removal of impacted surgical tools such as the chisel after cutting.

Referring now to FIGS. 25b-d, in use box chisel cutting head 266 is positioned in substantial alignment with a space 279 between adjacent vertebrae endplates 277 and 278. Non-cutting edges are inserted into space 279 with guiding portions 296 and 298 engaging endplates 277 and 278. Cutting head 266 is then advanced, by use of a slap hammer if necessary, with blades 268 and 270 removing the tissue of endplates 277 and 278, respectively, disposed between the guide portions and the blades.

There is also provided in the present invention a novel retractor assembly as depicted in FIGS. 28-30. Nerve retractor assembly 330 includes retractor handle 346, retractor 340, and channel 352 for receiving retractor blade 342. Channel 352 of retractor 340 is provided in a shape to minimize the amount of retraction of the neural structure necessary to perform the procedures yet provide the surgeon with an unobstructed view of the intervertebral space. Channel 352 and retractor blade 342 are illustrated in FIGS. 28 and 30 as having a generally concave shape. It is also considered within the scope of the present invention to provide channel 352 and retractor blade 342 in alternative shapes to meet specific needs to gain access to a surgical site.

Nerve retractor assembly 340 also includes at least one, preferably two, supporting members positioned on opposing sides of channel 352. Preferably channel 352 includes at least one, preferably two, enlarged edges 347 and 349. Enlarged edges 347 and 349 can be adapted for receiving pin drive shaft 334. In addition,

enlarges edges 347 are adapted to receive and hold retractor blade 342. Retractor blade 342 may be inserted from the top portion of channel 352 adjacent shoulder 354 and slidably advanced toward distal end 351. Blade 342 is retained in place by enlarged edges 347 and 349, as well as surface 358. Retractor blade 342 further includes a distractor tip 344 sized to be inserted into a disc space to achieve or maintain distraction. It will be understood that the width of tip 344 may be varied depending on the amount of distraction desired. Moreover, while pins 336 and 338 are disclosed for maintaining the position of the retraction assembly, it is contemplated that the engagement of retractor blade 342 in the disc space may be sufficient to hold the retraction assembly without the use of pins 337 and 338.

In alternative embodiments, pin 336 includes threads for threading engagement in internal threads (not shown) of supporting member 347. Thus, pin 336 can be anchored to the channel of retractor 340. Pin 336 includes pin driver handle 332, pin driver shaft 334, which can include a lower portion which is slidably engaged in support member 350. Pin 336 includes at its distal end a tissue engagement end 337. A second pin 338 can be mounted on a second supporting member 350. After manipulation of the spinal structures using retractor blade 342 and retractor 340 to provide sufficient room to proceed with the PLIF operation, tissue engaging end 337 of pin 336 is forcibly inserted into tissue such as bone to secure the retractor blade and the retracted neural structures. Alternatively, the second pin 338 can be used to initially position and secure one side of nerve retractor assembly 330 relative to the nerve structure. After the pin has been used to secure one side of the retractor, the retractor can be used to engage and manipulate the selected nerve structure. After the nerve structure has been sufficiently retracted a second pin is forcibly inserted into tissue.

Retractor blade 342 is provided in a shape that can be nested in channel 352 to ensure that the surgeon has an unobstructed view of the surgical site. Retractor blade 344 includes lead ends of retractor 344 opposite stop 343. Stop 343 is inserted into opening 341 on retractor 340. Preferably stop 343 extends through opening 341 and engages shoulder 354 to secure retractor blade to retractor 340.

There is also provided in the present invention a distractor as depicted in FIGS. 31 and 31a. Distractor 370 includes coupling 372 attached to one end of shaft 374 and a distractor head 376 disposed opposite coupling 372 on shaft 374. Distractor head 376 is substantially in the form of a wedge shape, wherein distractor tip 379 forms the apex of the wedge. Preferably, distractor tip 379 contains a blunt edge. Distractor head 376 includes large side 380 and a corresponding large side opposite 380 to form the large side of a wedge. The large side of distractor head 376 is defined as having a length illustrated by reference line 384. Similarly, small side 382 and corresponding side opposite 382 form the short or small side of the wedge having a width illustrated by reference line 386. Furthermore, the detractor head includes a series of index markings 378 which index the depth the retractor is inserted into tissue.

Additional cutting instruments are provided for use with the present invention. For example, shaver 280 illustrated in FIG. 26 is provided with a cutting head 286, shaft 284, and handle 282. Handle 282 includes a receptacle 283 for attachment of a slap hammer. Cutting head 286 includes upper shaving blade 288 and lower shaving blade 290 provided between first arm 287 and second arm 289. Upper and lower shaving blade 288 and 290 are orthogonal to first and second arms 287 and 289 such that when the upper or lower shaving blade 288 or 290 or both are raked across tissue surfaces, the blades cut or scrape away a portion of tissue surface. Cutting head 286 also includes a series of index markings to determine the depth of the scraper head in tissue.

Round scraper illustrated in FIGS. 32-32f is provided for use with the present invention. Round scraper 390 includes shaft 402 and scraper head 392. Shaft 402 defines a longitudinal axis 391. Scraper head 392 includes a first arm 393 and a second arm 395. Shaft 402 includes a tapered neck 403. First arm 393 and second arm 395 define a cavity 398 for receipt of cutting debris. Attached to first and second arm 393 and 395 are rounded scraper edges 394 and 396. First arm 393 and second arm 395 are attached to curved tip 404. Rounded scraper edges 394 and 396 are backward-facing cutting edges, which can cut bone or other tissue as the round scraper 390 is withdrawn from the disc space. Round scraper edges 394 and 396 are

provided to allow simultaneous cutting on opposing surfaces of adjacent vertebral bodies. First arm 393 includes an upper surface 397 and a lower surface 400. Upper surface 397 and lower surface 400 are substantially flat. Second arm 395 includes similar structures. Upper surface 397 and/or lower surface 400 allow for controlled
5 scaping of the disc space by contacting either the upper or lower vertebral body. Furthermore, the flat upper and lower surfaces 397 and 400 and tapered neck 403 are adapted to provide enhanced viewing of the disc space. It is important to be able to view the disc space while positioning the round scraper 390 in the disc space to remove bony tissue. Round scraper 390 is provided for preparing a bottom of the
10 preformed cavity for proper seating of implants as depicted in the present invention.

There is also provided in accordance with the present invention a plane scraper 410 illustrated in FIGS. 33 through 33c. Plane scraper 410 includes scraper head 412. Scraper head 412 is adapted to provide a plurality of plane scraper blades 414 and
15 416. Plane scraper blades 414 and 416 are integrally attached to first arm 415 and second arm 417. One or both of first arm 415 and/or 417 include index markings 418 to indicate the depth the plane scraper is inserted into the cavity. First and second arm 415 and 417 define a cavity 420 for receipt of bone cuttings and debris.

As shown in FIG. 34, there is also provided in accordance with the present invention rotatable cutter 430. Cutter 430 includes handle 432, shaft 434, and cutter
20 head 436. Cutter head 436 includes first cutting arm 437 and second arm 439. First cutting arm 437 and second cutting arm 439 are spaced apart and define a cavity 448 therebetween for receipt of cutting debris. First cutting arm 437 includes at least two cutting blades. For example, FIG. 34a depicts cutting arm 439 having a first cutting blade 438 and opposite second cutting blade 440. First and second cutting blades
25 extend longitudinally and are positioned to lie parallel to the longitudinal axis of rotatable cutter 430. Similarly, cutting arm 437 is provided with a first cutting blade 442 and a second cutting blade 443. Rotatable cutter 430 is provided for use in a disc space to cut adjacent endplates of adjacent vertebrae by a twisting the cutter. As with other instruments, the cutting head includes index marks 441 to indicate the depth the
30 rotatable cutter is inserted into tissue.

Referring to FIG. 35, also toothed scraper 460 is provided in accordance with the present invention. Toothed scraper 460 includes handle 462, shaft 464, shaped flat distal end 466, and cutting head 468. Cutting head 468 includes a plurality of scraper edges, each scraper edge having a series of teeth 471. In preferred
5 embodiments, scraper head 468 includes first scraper edge 470 and second scraper edge 472. Scraper head 468 culminates in a curved distal end 474. As with other instruments provided in accordance with the present invention, cutting head 468 includes index markings 476 to indicate the depth the cutter is inserted into tissues.

A preferred embodiment of protective guide sleeve 510 is illustrated in FIG. 36.
10 Protective sleeve 510 includes hollow body 512. In preferred embodiments, hollow body 512 is provided in the form of a hollow rectangular tube. Hollow body 512 includes a seating end 516, which is open and provides access to the interior of hollow body 512. Hollow body 512 also includes an opposite end that branches into a first distractor fin 518 and second distractor fin 520 extending from end 517. First
15 distractor fin 518 is provided with inclined surface 526, which tapers to reduce the width of distractor fin 518. Distractor fin 518 furthermore culminates in a first curve tip 522. Second distractor fin 520 also includes an inclined surface 528 and culminates in curve tip 524. Positioned between the seating end 516 and first and second distractor fins 518 and 520 is viewing aperture 514. Viewing aperture 514 is
20 provided for visualization of the interdisc space and viewing the index marks on the instruments that are inserted through the interior core 513 of hollow body 512. Use of protective sleeve 510 allows a surgeon to minimize incised area and exposure of internal tissue during posterior lumbar interbody fusion surgical procedures. The protective sleeve 510 provides protection for neural structures. Furthermore, seating
25 end 516 of protective sleeve 510 provides a surface for engaging depth stops on surgical instruments to control cutting bony surfaces and countersinking implants.

A number of surgical instruments are illustrated in FIGS. 37a-40c that can be used in conjunction with guide sleeve 512. These instruments include many of the same features, benefits and aspects as have already been disclosed in the above
30 description. In addition, these instruments include additional features and objects. These instruments are adapted to be received within the interior region of guide sleeve

512. In general, these surgical instruments include a shaft attached to a surgical head adapted to be received within the interior region of a guide sleeve.

Yet another embodiment of a box chisel is illustrated in FIGS. 37a-38. Similar to the embodiment depicted in FIG. 25, Chisel 550 comprises a cutting head 551 that includes first non-cutting edge 554, second non-cutting edge 556 an upper cutting blade 558 and a lower cutting blade 560. Cutting head 551 includes internal cavity 557. Chisel 550 further includes a shaft 552 that is adapted to be received within the interior region 513 of protective guide sleeve 510 as illustrated in FIG. 38. Depth stop 562 is mounted on shaft 552 to prevent the chisel from cutting deeper than a predetermined depth by contacting seating end 516 on protective sleeve 510. In a preferred embodiment illustrated in FIG. 38, depth stop is threadedly mounted on shaft extension 564 so that rotation of depth stop 562 about the shaft adjusted the depth of cut. Depth indicator marks 566 on shaft extension 564 indicate the depth the chisel will cut when the depth stop 562 has contacted seating end 516.

Referring now to FIGS. 39a-39f, another embodiment of an implant holder is illustrated. The implant holder 570 includes a gripping head 572 shaft 574 and handle 576. As with other embodiments of the implant hold described for use with the present invention, implant holder 570 releaseably secures and impacts an implant into a preformed cavity. Gripping head 572 includes structural features for both securely gripping the implant and for driving the implant. For example, in the preferred embodiment illustrated in FIGS. 39e and 39f, gripping head includes a roughened impacting surface 576. Roughened impacting surface 576 is provided substantially orthogonal to the direction the implant is impacted into the vertebral body. The roughened surface provides frictional engagement with the tool engaging end of the implant and in combination with a second structure such as a second surface 578, inclined surface 579 or a shaft extension 580 secure the implant to the gripping head during the PLIF operation. Once the implant has been driven into the vertebra body, the implant is released from the gripping head.

Yet another embodiment of the implant holder is illustrated in FIGS. 40a-40c. Implant holder 590 includes griping head 591, shaft 592, depth stop 593, and handle 594. Gripping head 591 includes an impacting surface 595. Preferably impacting

surface 595 is roughened or knurled. Gripping head 591 also includes a second surface 597, which is substantially orthogonal to impacting surface 595. A third inclined surface 598 abuts opposite end of impacting surface 595 from second surface 597. Shaft extension 599 protrudes through impacting surface 595 to be received
5 within shaft 592. Handle 594 includes shaft extender 600, which is rotatably mounted on handle 594. In preferred embodiments, shaft extender 599 extends through shaft 592 and handle 594 and includes external threads that are matingly received in internal threads on shaft extender 600. Gripping head 591 includes structural features for both securely gripping the implant and for driving the implant into intervertebral
10 space. For example, impacting surface 595 in combination with a second surface 597 and/or incline surface 598 secure the implant to the gripping head. Preferably, shaft extension 599 matingly engages in a tool-engagement recess on an implant. In preferred embodiments, shaft extension 599 is radiopaque and extends through implant body to or through the insertion end. Radiopaque shaft extension 599
15 provides a means for viewing the seating of an implant during surgery via radiography.

Implant holder 590 can be used with protective guide sleeve 510. Gripping head 591 and shaft 592 can be adapted to be slidably received within the interior region 513 of guide sleeve 510. Depth stop 593 on implant holder 590 is adapted to
20 engage or contact the seating end 516 on guide sleeve 510.

In one preferred embodiment, implant holder 590 includes shaft 592, which is provided with a square or rectangular cross-section and adapted to be matingly received with a square or rectangular protective guide sleeve. Mating engagement of implant holder 590 within protective sleeve 510 correctly centers implant holder 590
25 and a secured implant in the prepared vertebral space.

Depth stop 593 can be provided on shaft 592 in a fixed position or a variable position. Varying the position of depth stop 593 on shaft 593 allows for depth control during impaction of implant into the prepared vertebral space.

There is also provided in accordance with the present invention a bone graft
30 loader 670 illustrated in FIGS. 41 and 42. Bone graft loader 670 includes plunger 672, depth stop 674, pivot plate 678 pivotally mounted with pivot pin 676 to loader

shaft 680. Loader shaft 680 includes a first surface 688, a second bottom surface 689, an insertion end 686 and a second end 687. In preferred embodiments, loader shaft 680 also includes third wall 691, and fourth wall 692. Fourth wall 692 opposite first wall 688 includes opening 682 proximal to mounting surface 690 on pivot plate 678.

5 Plunger 672 includes a first end 693 that is positioned within loader shaft 680. Furthermore, plunger 672 is adapted to be slidably received within loader shaft 680 such that plunger 672 is disposed between pivot pin 676 and first surface 688. In a first position first end 693 of plunger 972 is proximal to depth stop 674 and disposed within loader shaft 680 between to pivot pin 676 and first wall 688. In a second

10 position plunger 672 is proximal to insertion end 686 and within loader shaft 680 and disposed between pivot plate 678 and first wall 688. Pivot plate 678 is pivotally mounted to loader shaft 680 with pivot pin 676 and disposed within loader shaft 680 in a first position in a substantially a diagonal direction from pivot pin 676 to insertion end 686. In a second position pivot plate is disposed within loader shaft 680 to lie

15 substantially parallel to fourth wall 692. Pivot plate 678 includes a mounting surface 690 for receiving osteogenic material 684. Opening 682 provides access to the interior of loader shaft 680 for receipt of osteogenic material, which can be deposited on mounting surface 690.

Referring additionally to FIGS. 43a and 43b. Bone loader 670 can be adapted to

20 be slidably received within protective guide sleeve 510. Loader shaft 670 can be used to pack osteogenic material, such as morselized bone graft, into the intervertebral space. The morselized bone graft can be packed either prior to insertion of an implant or subsequent to insertion of an implant. Osteogenic material 684 is packed onto mounting surface 690 through opening 682 while plunger 672 is in a first position

25 distal from insertion end 686 of shaft 680. Bone graft loader 670 is then inserted into guide tube 510 position insertion end 686 within the intervertebral space such that opening 682 opens either laterally or medially within the intervertebral space. Plunger 672 is pushed into loader shaft 680 in a direction toward insertion end 686. When plunger 672 is thus disposed within loader shaft 680, pivot plate 678 is

30 disposed against fourth wall 692 and the osteogenic material 684 is forced through opening 682 and into the intervertebral space.

Bone graft loader 670 can also be used to anteriorly position osteogenic material in the intervertebral space. Plunger 672 is pushed part way into loader shaft 600 to dispose pivot plate 678 against fourth wall 692. Osteogenic material can be inserted into loader shaft 680 through opening 685 in insertion end 686. Insertion end 686 can
5 be inserted into the disc space preferably through protective guide sleeve 510. Forcing plunger 672 fully into loader shaft 680 forces the osteogenic material into the disc space.

Reference to donor bone is understood, for the purposes of the present invention, to include cortical bone, cancellous bone, and any combination thereof, it
10 being understood that cortical bone typically demonstrates greater structural integrity and is therefore a preferred material for fashioning load-bearing implants.

There also is provided a method of providing implants by a more efficient use of donor bone. Current methodologies for providing cortical bone infusion implant spacers typically require cutting the spacer, usually in the form of a dowel, from the
15 diaphysis of a long bone. Only a certain portion of the diaphysis bone wall is sufficiently thick to provide dowels with requisite strength to maintain the intervertebral space. For example, in a human femur only about the middle third of the diaphysis, where the shaft is narrowest and the medullary canal is well formed, has sufficient thickness and density to be used to prepare cylindrical cortical dowels.
20 The suitable portions of the diaphysis are sliced and then a cylindrical plug is cut from each slice.

FIG. 44a illustrates bone slice 610 viewed from above, which was cut from the diaphysis of a long bone. The medullary canal 612 lies substantially in the center of the bone slice. Reference lines 616 and 617, which outline a pattern for cylindrical
25 dowel, are superimposed on bone slice 610. In FIG. 44b the bone slice 610 is viewed from the side, and pattern of the cylindrical bone dowel is defined by reference lines 616 and 617. The cylindrical bone dowels are cut from the bone slice then machined to form a cylindrical dowel having the desired shape and surface features. Most often the cylindrical dowels include the medullary canal to provide a depot for osteogenic
30 material and promote fusion of the adjacent vertebrae. Much of the donor bone is wasted as is illustrated in FIGS. 44a, 44b, 45 and 46. Remnant 620, which includes a

portion of the medullary canal 620 is often discarded. The present invention uses scraps such as remnant 620 to prepare implants. For example, remnant 620 may be used as a starting point to prepare a crescent shaped implant according to the present invention. In FIG 44c a cortical bone dowel is illustrated. Cortical bone dowel 622 is
5 formed from bone slice 610.

Referring now to FIGS. 47 and 48, portions of long bones segments from the upper or lower third of the diaphysis of long bones are illustrated. Nearer to the end of the bone the slices are taken, the more irregular shaped the slices become. Cortical bone walls become much thinner or the medullary canal in these portions of the bone
10 is not sufficient circular to be used to manufacture cylindrical dowels. The above-described bone segments are not suitable for the formation of cylindrical dowels. However, these segments of the long bones can be used to form the implants shaped according to the present invention. Moreover, utilization of the teaching of the present invention may yield a greater volume of implants from the same amount of
15 donor bone. While it is within the scope of this invention to use any suitable long bone, FIGS. 47 and 48 illustrate sections of humeral and tibial shafts. In FIG. 47 bone slice 640 is illustrated. A J-shaped implant 110 and two implants 10 having flat sides are superimposed in bone slice 640. In a preferred embodiment, three J-shaped implants can be prepared from a single bone slice. Similarly, the bone segment 641
20 of FIG. 48 may be divided into three crescent shaped implants. Crescent shaped implants 642, 644 and 646 are superimposed on bone slice

Implants prepared according to the present invention can include a portion of the exterior wall of a bone slice. In the J-shaped space superimposed on the bone slice 640, flat side 16 can include convex surfaces where flat side 16 abuts insertion
25 end 17 and tool engagement end 32. The curvature results from providing bone implants for the present invention through a more efficient use and conservation of donor bone. Bone implants such as dowels are formed from cross-sectional slices of long bones such as the femur, tibia and fibula. The remnants from this process include a curved surface formed from the outer walls of the bone slice. The most
30 efficient use of these remnants may require that flat side 16 be machined to include at least a portion of the curved surface.

Use of these previously undesirable donor portions in accordance with the present invention provides a more efficient use and conservation of a limited and very valuable resource of cortical donor bone.

5 The present invention also includes a method for fusing adjacent vertebrae. The patient is placed on the operating table in the prone position with lateral C-arm fluoroscopy. A midline incision provides the approach and exposure of the interlaminar space and facet joints at the affected level, which for this example is L4-5. The soft tissue exposure should also include the pedicle entry zone at L4 with care
10 taken to not disrupt the facet caps or ligaments at L3-4. Exposure of the dura is accomplished in a routine fashion with bilateral hemi laminectomy and medial facetectomy with care to save the morselized bone chips removed during this decompression. After the lateral dura and nerve root traversing the L4-5 level has been exposed on both sides, the facet should be removed laterally so that there is an
15 adequate exposure to the disc lateral to the L5 root bilaterally. An attempt to preserve some component of the L4-5 facet complex should be made if possible. The epidural veins are coagulated over the annulus or herniated disc and any tethering of the L5 root is dissected to allow for sufficient medial retraction of the dura and L5 root.

A conventional discectomy is performed by incising the annulus with preferably
20 a 15 scalpel blade and removing this annulus with a discectomy rongeur. This is done bilaterally, and then soft fragments from the intradiscal space or extruded fragments are removed with the discectomy rongeur in a conventional fashion. Loose intradiscal fragments are removed both medially and laterally into a depth of about 30 mm.

The remaining soft tissue or cartilaginous endplate coverings are scraped away
25 from the endplate using the round scraper 390. This vigorous scraping or curettage of the soft tissue endplate material is done starting medially under the midline and gradually working laterally in a sweeping motion until the upper and lower cartilaginous endplates have been cleared of the soft tissue. This is also performed bilaterally with the intent to create satisfactory endplate surface to promote fusion of
30 the endplate and morselized graft to be inserted in the disc space later in the procedure.

The disc space is then sequentially distracted until the original disc space height is obtained and the normal foraminal opening accomplished. This is done by inserting a 9 or 10 mm distractor 370 on one side, rotating it, and then taking a distractor 370 1 mm larger and inserting it in the opposite side, rotating it, and then alternating sides until the desired height is obtained. The largest distractors are left in the disc space in the distracted position while continued disc space preparation is performed on the opposite side.

Rotating cutter 430 is inserted into the non-distracted side and rotated to remove residual intradiscal material and create a channel in the dorsal-most endplate, removing osteophytes and facilitating placement of the guide tube anchoring fins. The rotating cutter 430 is inserted into a depth of about 30 mm, rotated and carefully lifted out, removing the soft tissue from the disc space. After using this on the left side, the distractor 370 is removed from the right, inserted on the left, distracted, and then the rotating cutter 430 is used on the right side in the same fashion. This is inserted and rotated until there is no further soft tissue removed from the disc space. After removing the rotating cutter, the discectomy ronguers may also be re-inserted to remove residual soft tissue. At this point, the disc space and opening is ready to accept protective sleeve 510.

Using fluoroscopic guidance, appropriate size guide sleeve 510 is selected, and with the dura retracted using flat, bayoneted, dura and nerve root retractor, protective sleeve 510 is seated down into the laminectomy defect and first distractor fin 518 and second distractor fin 520 are anchored into the disc space. Using the mallet, the guide sleeve is then impacted securely into the laminectomy opening with caution not to trap dura or the upper traversing root under the protective sleeve end 517. Once this has been seated on the disc space and the seating confirmed using fluoroscopic guidance, distractor 370 is removed from the opposite side, and the nerve root retractor is lifted out as well.

The appropriate box chisel 550 is then inserted into the guide tube and with the slap hammer or the mallet is impacted down into the disc space, cutting the tract in the endplate to accept the bone graft. This is done using fluoroscopic guidance to ensure that the upper cutting blades 558 and lower cutting blades 560 enter the disc

space and traverse in a parallel fashion to the endplates. The depth of the chisel may be adjusted by rotating depth 562 stop at the top of chisel 550. Once the chisel has been impacted to the desired depth, preferably about 23-28 mm, it is then removed using the slap hammer technique, carefully removing it from the disc space. After
5 removal of the chisel, whose internal cavity 557 may also include disc and endplate material, the discectomy rongeur is inserted down the guide tube to remove any further residual soft tissue.

The side-loading morselized bone graft loader 670 is then loaded with an alloquat of morselized autologous or autograft bone and then inserted into the guide
10 sleeve 510 with the side opening 682 aimed laterally. Once the bone graft loader 670 is fully inserted in the guide sleeve 510, the piston 672 is impacted down the loader shaft 680 delivering the morselized bone laterally. The bone graft loader 670 is then removed in this "delivered position," the piston removed from the loader shaft 680, and the second alloquat of bone inserted in the bone graft loader. The bone graft
15 loader 682 is then again inserted and aimed with the opening 602 aimed medially. When fully inserted, an alloquat of morselized bone is then delivered medially under the midline. The bone graft loader is once again removed, and the disc space is ready to accept the structural allograft.

The appropriate-sized implant 210 is then attached to implant holder 570 and
20 the shaft extension 580 is fully extended by turning extension knob 582, seating the graft on the loader firmly. It is then placed in the guide sleeve 510 and impacted into the disc space to the desired depth. The shaft extension 580 is then unscrewed from the graft and then implant holder 570. The guide sleeve 510 is also then removed from disc space and the discectomy and graft site inspected. The epidural space is
25 then temporarily packed with gel foam for hemastasis, and the entire procedure is again repeated on the opposite side.

After the interbody grafts have been securely placed and their location confirmed using fluoroscopy, the large rongeur is used to remove the dorsal aspect of the L5 facet joint at the transverse process on the left side exposing the opening to the
30 L5 pedicle. Using a pedicle probe and with fluoroscopic guidance, the trajectory or path of the pedicle is identified, the pedicle probe is removed, and the appropriate-

sized tap inserted down the pedicle, followed by the DYNA-LOK[®] pedicle screw.

This same procedure is repeated at L4 with care taken not to disrupt the facet joint or ligament at L3-4. The lateral aspect of the facet and transverse process at the junction are removed with the rongeur followed by the probe, tap, and then pedicle screw.

5 This is again repeated on the opposite side. When all four screws have been placed, the titanium plate is seated down over the pedicle screws. The residual morselized bone from the laminectomy and facet is packed laterally over the residual facet joint and medial transverse processes and then the locking screws are seated down onto the plate, and pedicle screws tightened to secure the plates to the pedicle screws. If
10 necessary, a compressor is used to place compression forces on the pedicle screws as the nuts are being tightened down. After the nuts have been tightened, the epidural space is once again inspected for appropriate decompression of the L4 and L5 nerve roots, hemostasis is obtained using the gel foam sponge, and then the wound is closed in layers after irrigating with vast tracent solution. Care is taken to close the fascia
15 securely and attach it to the residual spinous process and interspinous ligament if possible.

It is understood to those skilled in the art that the above procedure can be directed to a transforminal procedure using a far lateral PLIF approach through the facet joint. Typically the facet joint is removed to provide an approach to the disc
20 space in an oblique orientation relative to the posterior vertebral body. This provides access to the disc space with minimal retraction of the dural structure and nerve roots.

While the invention has been illustrated and described in detail in the drawings and the foregoing description, the same is considered to be illustrative and not restrictive in character. It is understood that only the preferred embodiments have
25 been shown and described and that all changes and modifications that come within the spirit of the invention are desired to be protected.

We claim:

1. A spinal fusion implant, comprising:
a bone portion having an upper bone engaging surface, a lower bone
5 engaging surface, a first sidewall and an opposite second sidewall
extending between said upper and lower bone engaging surfaces, said first
sidewall having a portion defined by a concave surface.
2. The implant of claim 1, wherein said bone portion is formed from a
10 donor bone segment defining at least a portion of a medullary canal and
said concave surface defines a portion of said medullary canal.
3. The implant of claim 1, wherein said upper and lower bone
engaging surfaces include a roughened surface.
15
4. The implant of claim 3, wherein said roughened surface includes
grooves.
5. A spinal fusion implant formed from bone, the implant comprising
20 a first end adapted to receive an implant tool, the first end having at
least one tool engaging recess provided for mating engagement with a
projection on an implant insertion tool;
a second end distal from the first end; and
an elongated body disposed between said first and second ends and
25 defining a longitudinal axis along a length of the implant and wherein the
body is provided with a concave surface wherein at least a portion of the
concave surface approximates a section of the medullary canal from a long
bone.

6. The implant of claim 5 wherein the at least one tool engaging recess defines an elongated cylinder having an axis substantially parallel to the longitudinal axis.
- 5 7. The implant of claim 5 wherein the at least one tool engaging hole includes a threaded bore.
8. The implant of claim 5 wherein the at least one tool engaging hole includes a substantially smooth bore.
- 10 9. The implant of claim 5 wherein the at least one tool engaging hole extends through the implant.
10. The implant of claim 6 wherein the at least one tool engaging hole
15 extends to a depth of about 80% of the length of the body.
11. The implant of claim 5 wherein the elongated body further comprises at least one tool engaging recess defining an cylinder having an axis substantially perpendicular to the longitudinal axis.
- 20 12. The implant of claim 11 wherein the body further includes a slot surrounding the at least one tool engaging recess.
13. The implant of claim 5 wherein the second end includes a curved
25 surface.
14. The implant of claim 5 and further including at least one aperture extending therethrough for receiving osteogenic material.
- 30 15. The implant of claim 5 further comprising an osteogenic material packed within the a recessed area defined by the convex surface.

16. The implant of claim 15 wherein the osteogenic material is selected from a group consisting essentially of autograft, allograft, xenograft, demineralized bone, a calcium phosphate material, or bioceramic, a
5 bioglass, an osteoinductive factor resorbable plastic polymer composite or mixtures thereof.
17. The implant of claim 5 wherein the body is about 15 to about 30
10 mm long.
18. The implant of claim 5 wherein the outer surface further includes ridges for engaging bone surfaces.
19. The implant of claim 5 wherein the body is prepared from cortical
15 bone.
20. The implant of claim 5 wherein the body includes cancellous bone tissue.
- 20 21. The implant of claim 5 wherein the body is provided substantially in the form of a J-shape and wherein the concave surface defines the crook of the J-shape.
22. The implant of claim 21 wherein the tool receiving recess defines a
25 slot positioned substantially perpendicular to the longitudinal axis.
23. The implant of claim 21 wherein the body further includes tool insertion recesses.
- 30 24. The spinal fusion implant of claim 21 wherein the outer surface further includes surface features for engaging bone.

25. The implant of claim 5 wherein the body is substantially crescent shaped.
- 5 26. The implant of claim 25 wherein the at least one tool engaging recess defines a cylinder having an axis substantially parallel to the longitudinal axis.
- 10 27. The implant of claim 25 wherein the at least one tool engaging recess defines a cylinder extending through the implant.
28. The implant of claim 25 wherein the at least one tool engaging recess defines a cylinder extending about 80% of the length of the body.
- 15 29. The implant of claim 27 wherein the tool engaging recess defines a cylinder having a smooth bore.
30. The implant of claim 24 wherein the tool engaging recess defines a cylinder having internal threads.
- 20 31. The implant of claim 22 wherein the implant includes an outer surface having a series of ridges for engaging bone surfaces.
- 25 32. A spinal fusion implant for positioning within a cavity in an intervertebral space defined by the inferior surface of a first vertebra and an opposing superior surface of an adjacent second vertebrae, wherein the implant is formed from a portion of a diaphysis of a long bone having a medullary canal, said implant comprising:
- 30 a first end adapted for engaging an implant holder the first end having at least one tool engaging recess provided for matingly engagement of a projection on an implant tool,

a second end distal from the first end; and

an elongated body disposed between the first and second ends and defining a longitudinal axis along a length of the implant and wherein the body is provided with an upper bone engaging surface, a lower bone
5 engaging surface, and a concave surface extending between said upper and lower bone engaging surfaces, wherein at least a portion of the concave surface is formed from a section of the medullary canal from the long bone.

33. The spinal fusion implant of claim 32 wherein said concave surface
10 and the inferior and superior surfaces define a chamber for receiving osteogenic material.

34. An implant holder for releaseably securing a spinal fusion implant,
the holder comprising:
15 a shaft defining a proximal end and an opposite distal end with a longitudinal axis extending between said proximal and distal ends, said shaft including an upper branch, a lower branch and a channel therebetween; and
a gripping head attached to said distal end, said gripping head including an
20 upper branch extension attached to the upper branch, a lower branch extension attached to the lower branch, wherein the lower branch extension includes an impacting first surface and a second surface abutting the first surface and positioned to lie substantially parallel to the longitudinal axis
and wherein the upper branch extension includes an impacting third surface
25 and a fourth surface extending distally beyond said lower branch extension and adapted to matingly engage one side of a secured implant; and
a closure device movably mounted on said shaft, said closure device movable between a holding position urging said upper and lower branches together and a released position allowing movement of said upper and
30 lower branches.

35. The implant of claim 34 wherein the impacting first surface and impacting third surface includes an implant engaging projection.
36. The implant holder of claim 34 wherein the second surface is adapted to matingly engage a tool engaging recess in an implant.
37. The implant holder of claim 36 wherein the shaft further includes a coupling point for attaching a handle or an impacting tool.
38. An implant holder for releaseably securing a spinal fusion implant, the holder comprising:
a shaft defining a longitudinal axis and having a proximal end and an opposite distal end;
a gripping head attached to the distal end of the shaft, the gripping head provided with an impacting first surface positioned to lie substantially perpendicular to the longitudinal direction and a second surface abutting the first surface and substantially perpendicular to the first surface, the second surface adapted for controlling lateral motion of a secured implant; and
a pin extending from the first surface substantially parallel to the longitudinal axis.
39. The implant holder of claim 35 wherein a portion of the pin is radiopaque.
40. The implant holder of claim 38 wherein the shaft is hollow and the gripping head further includes a passageway through the first surface and into the shaft for receiving said pin therein.
41. The implant holder of claim 40 wherein the shaft includes means for extending said pin.

42. The implant holder of claim 40 wherein the second surface abuts the first impacting surface and defines an included obtuse angle with the first impacting surface.
- 5 43. The implant holder of claim 35 wherein the second surface abuts the first impacting surface and defines an included acute angle with the first impacting surface.
- 10 44. The implant holder of claim 45 wherein the gripping head further includes a third surface abutting the first surface and positioned to lie substantially parallel to the longitudinal axis.
- 15 45. The implant holder of claim 40 wherein the impacting first surface is roughened.
46. A chisel for cutting tissue from a first inferior surface of a first vertebrae and an opposing second superior surface of a second vertebrae adjacent to the first vertebrae, the chisel comprising:
- 20 a shaft; and
- a cutting head mounted on the second end of the shaft, the cutting head including a first non-cutting edge attached to a first arm, a second non-cutting edge attached to an opposite second arm and a first cutting blade and a second cutting blade disposed between said first and second arms wherein said first non-cutting edge and said second non-cutting edge
- 25 extend distally beyond said first and second cutting blades, thereby contacting the first and second surfaces to guide the first and second cutting blades.
- 30 47. The chisel of claim 46 wherein the cutting head further includes index markings for determining the depth of cut.

48. The chisel of claim 46 wherein the shaft further includes a depth stop.

5 49. The chisel of claim 46 wherein the shaft is adapted to be sliceable received within a guide sleeve.

50. A nerve retractor assembly for manipulation of the spinal neurostructure, the assembly comprising,
10 a retractor blade;
a retractor body adapted for unobstructed view of the retracted area wherein the retractor body is provided with a channel adapted to receive the retractor blade.

15 51. The nerve retractor assembly of claim 50 wherein the retractor body further includes at least one supporting member mounted thereon for attaching a retractor pin, and
at least one retractor pin attached to the supporting member for fixedly positioning the retractor blade relative to the neural structure.

20 52. The nerve retractor assembly of claim 50 wherein the at least one supporting member defines a hollow tube for receiving a retractor pin.

53. The nerve retractor assembly of claim 50 wherein the blade channel
25 is a concave channel.

54. The nerve retractor assembly of claim 50 and further including a second retractor pin having a handle and a shaft disposed between the pin and the handle and slideably received in the at least one supporting
30 members.

55. A nerve retractor assembly for manipulation of the spinal neurostructure, the assembly comprising:
a retractor body adopted for undistracted view of the retracted area, the retractor body including at least one supporting member mounted thereon for attaching a retractor pin, and
at least one retractor pin attached to the supporting member.
56. A method of preparing intervertebral space for receiving a posterior lumbar interbody fusion implant, the method comprising:
preparing a precise cavity in the intervertebral space by removing a portion of opposing surfaces of adjacent vertebrae defining the intervertebral space using the chisel of claim 46.
57. A method of restoring disc height and biomechanical stability to patent after discectomy, the method comprising:
distracting two adjacent vertebrae to provide a desired intervertebral space height;
preparing opposing surfaces of the two adjacent vertebrae to provide a cavity for receiving a spinal fusion implant using the box chisel of claim 46; and
inserting a spinal fusion implant in the cavity.
58. A method of preparing a implant for a posterior lumbar interbody fusion, the method comprising forming an implant having a substantially elongated body from a bone remnant left from the manufacture of a bone dowel from a long bone.
59. The method of claim 58 wherein the implant has sufficient width to withstand a compressional force of about 30,000 Newtons.

60 A round scraper for removal of tissue, the round scraper defining a longitudinal axis and comprising:

 a first arm extending substantially parallel to the longitudinal axis,

5 a second arm spaced from the first arm and extending substantially parallel to the longitudinal wherein the first arm and the second arm define a cavity therebetween, and

 a tip disposed between the first arm and the second arm wherein the tip includes a first upper cutting edge and a second lower cutting edge and a curved surface disposed between the first cutting edge and the second cutting edge.

10

61. The round scraper of claim 60 wherein the first arm further includes a first upper flat surface and a second lower flat surface and the second arm further includes a third upper flat surface and a fourth lower flat surface.

15

62. A bone graft loader for depositing osteogenic material in an intervertebral space, the bone graft loader comprising:

 a body surrounding a hollow shaft wherein the body includes a first wall and a second wall, the second wall including an opening into the shaft,

20 a pivot plate pivotally mounted within the shaft and having a surface proximal to the opening wherein the surface is adapted for receipt of osteogenic material, and

 a plunger slidably received with the shaft and disposed between the pivot plate and the first wall.

25

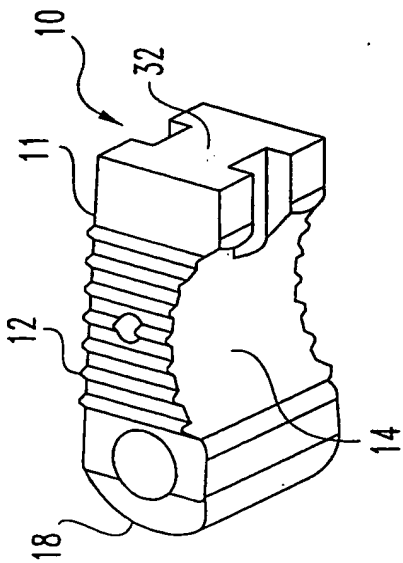


Fig. 1

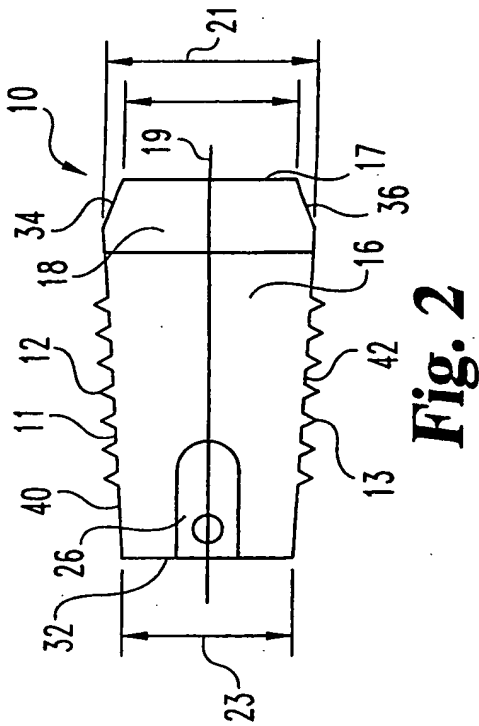


Fig. 2a

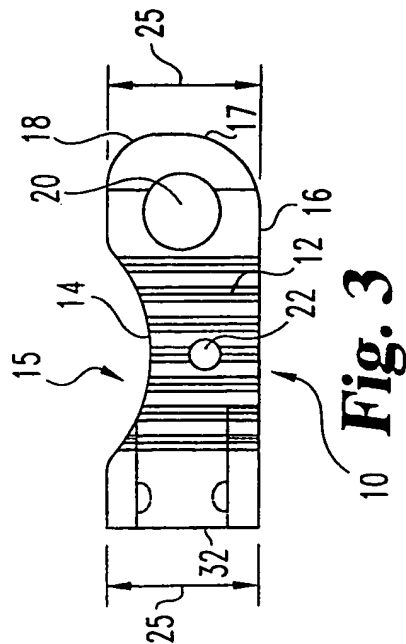
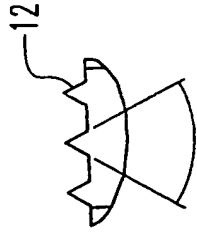


Fig. 3

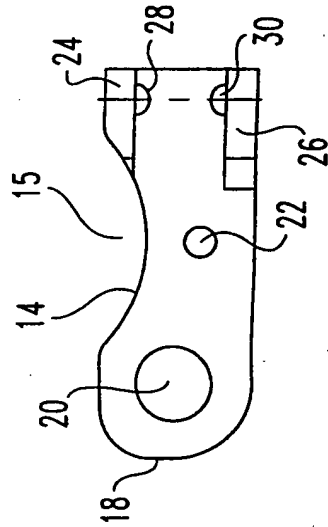


Fig. 5

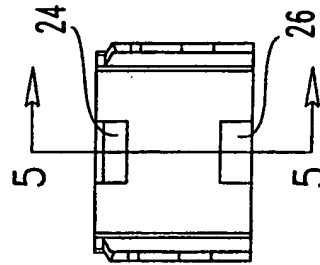


Fig. 4

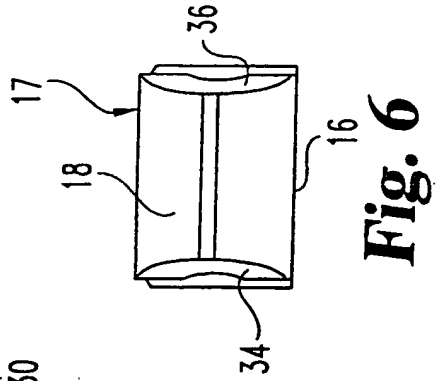
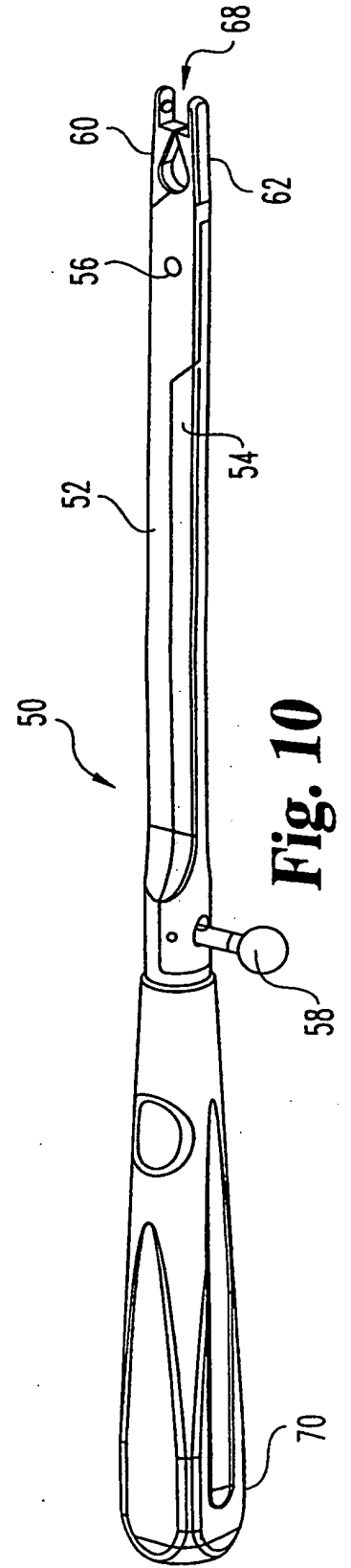
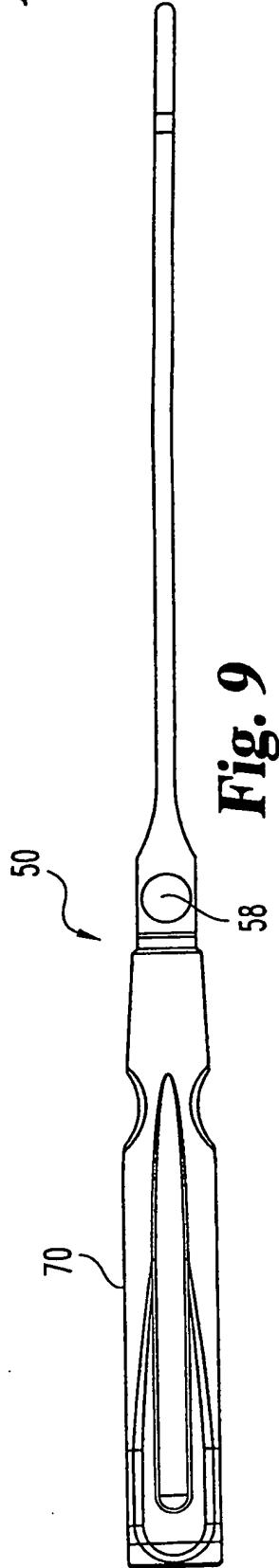
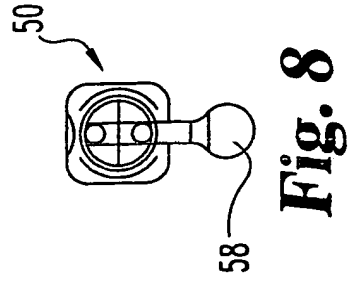
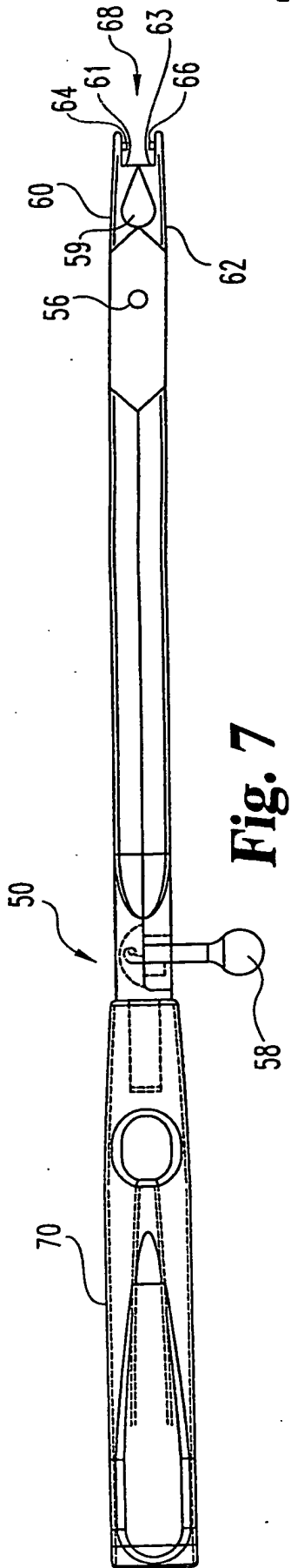
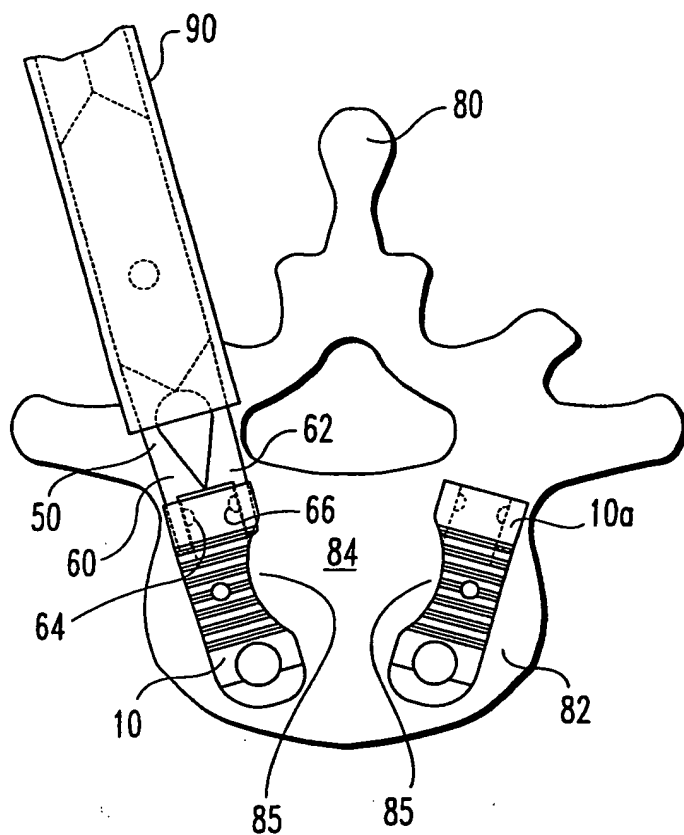
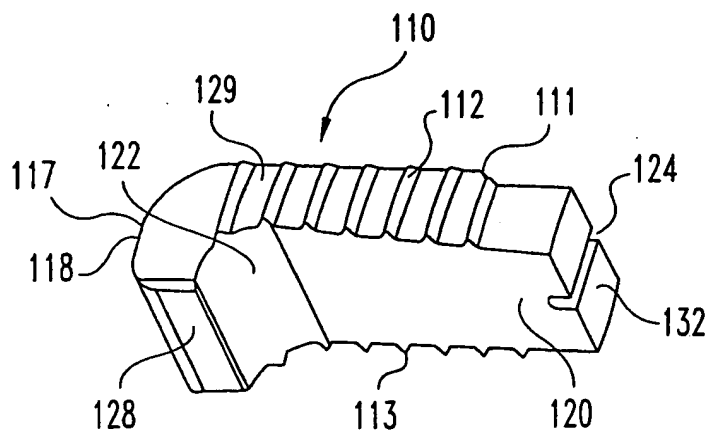
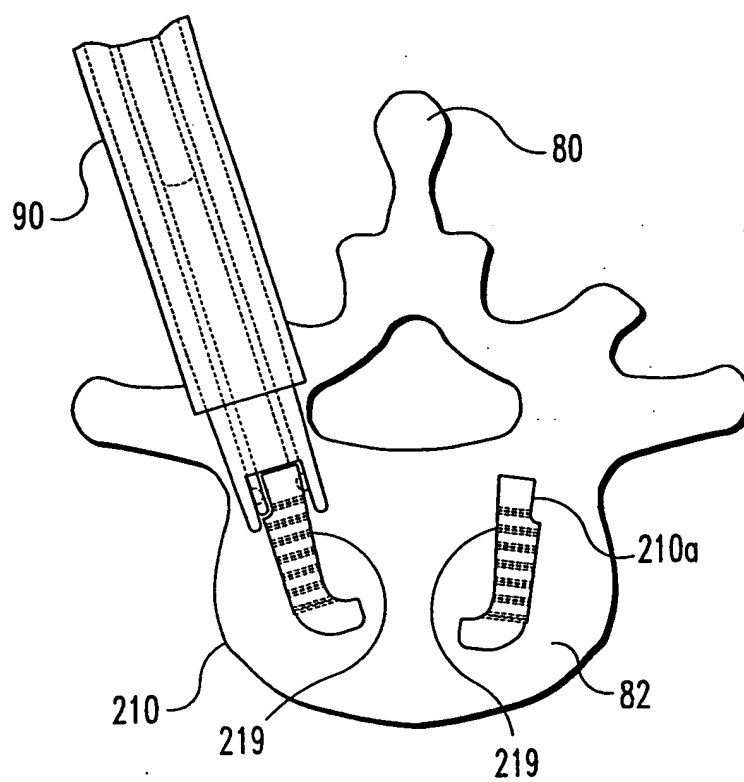


Fig. 6



**Fig. 11****Fig. 12**

**Fig. 11a**

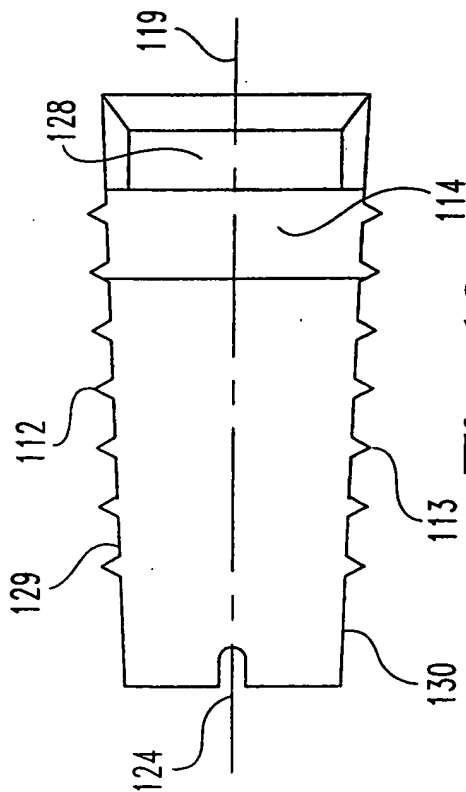


Fig. 13

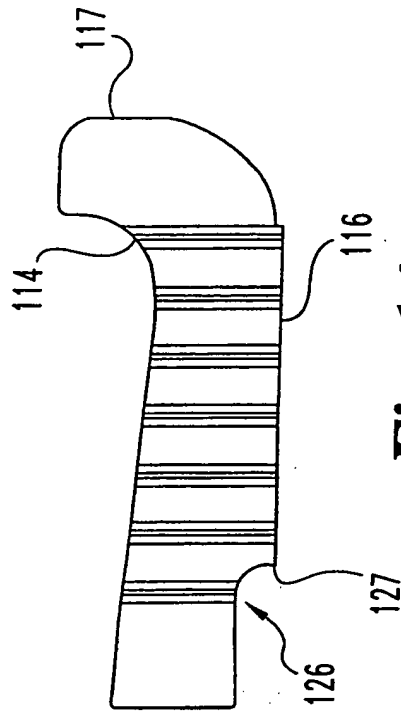


Fig. 14

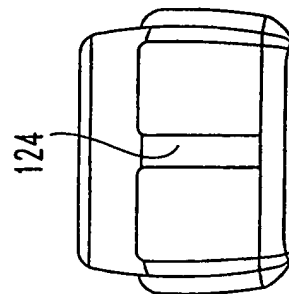


Fig. 15



Fig. 16

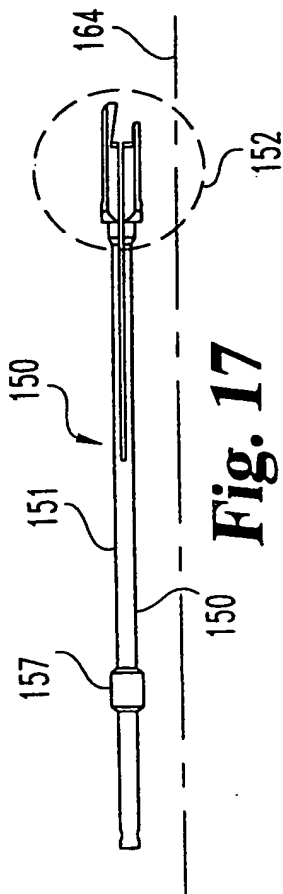


Fig. 17

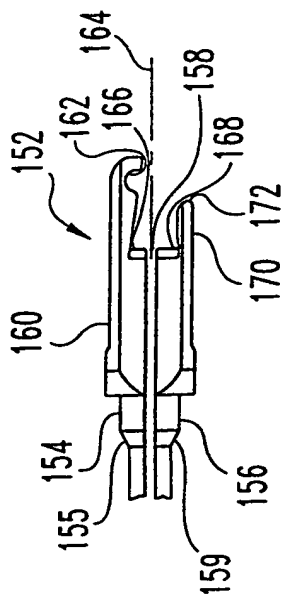


Fig. 17a

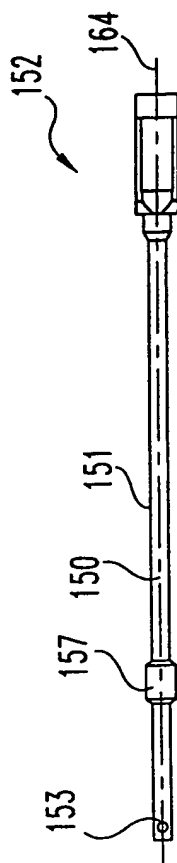


Fig. 18

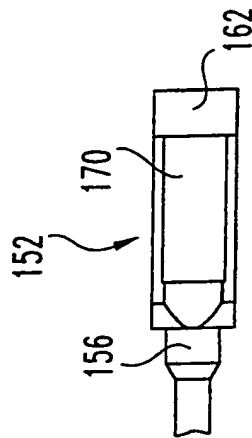


Fig. 18a

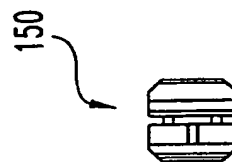


Fig. 18b

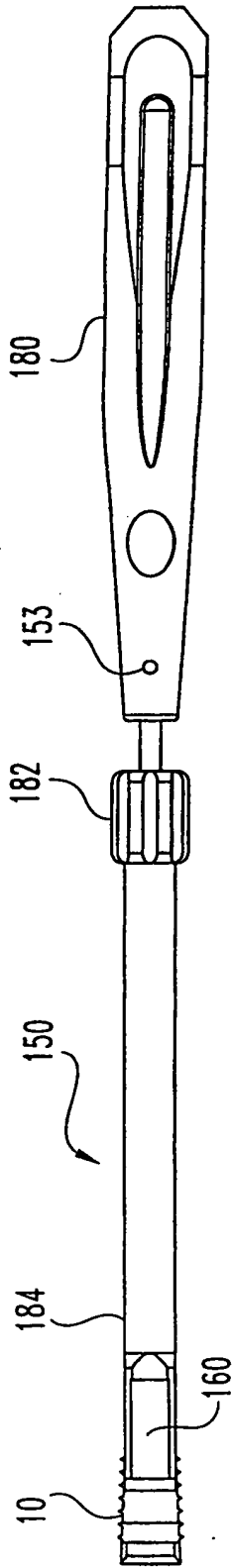


Fig. 19

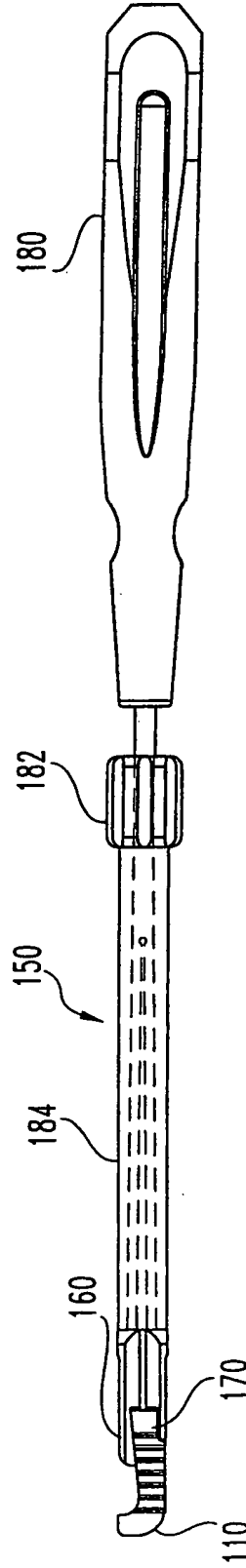


Fig. 20a

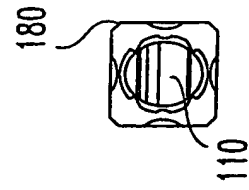


Fig. 20b

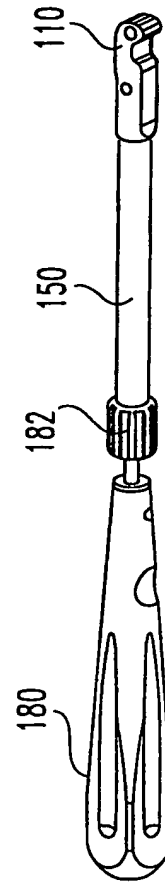
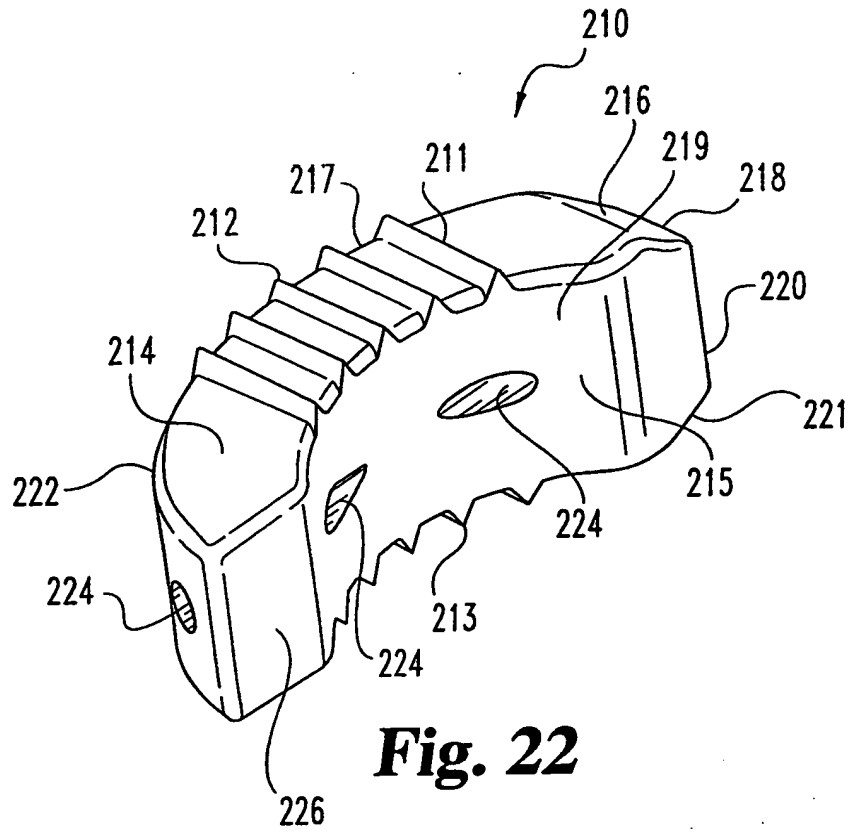
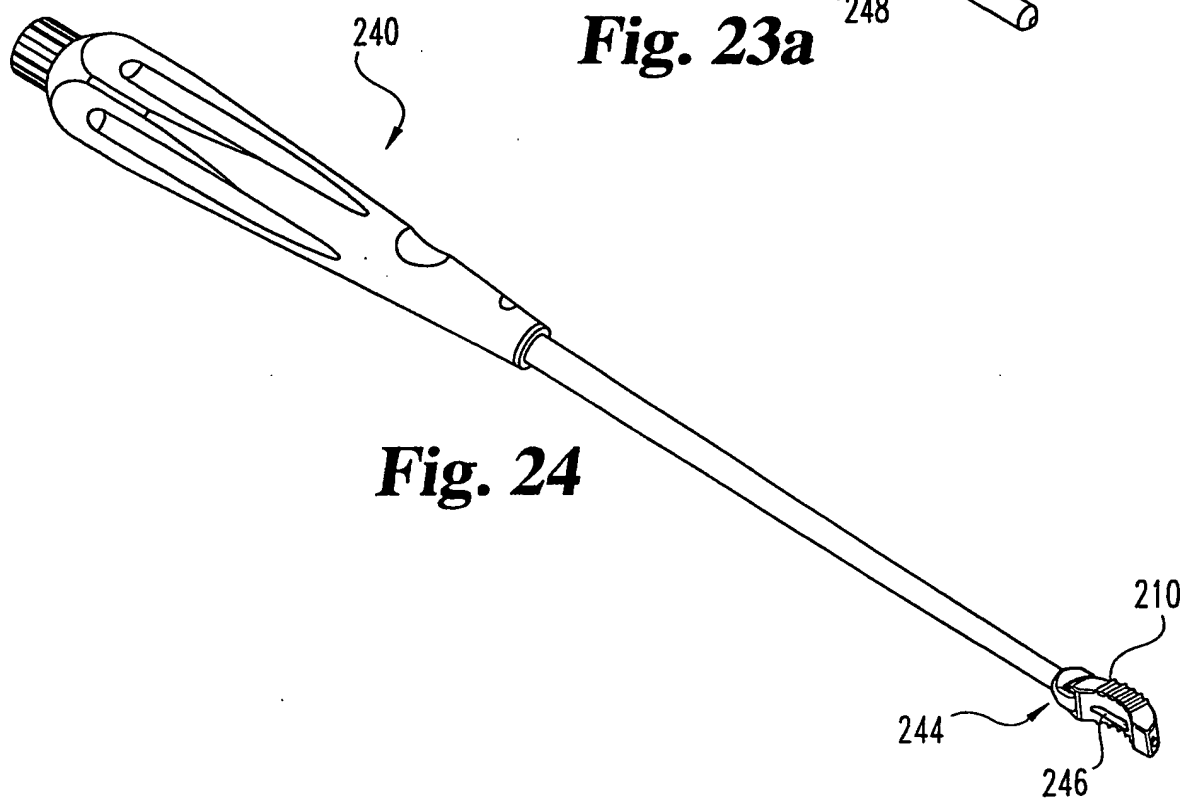
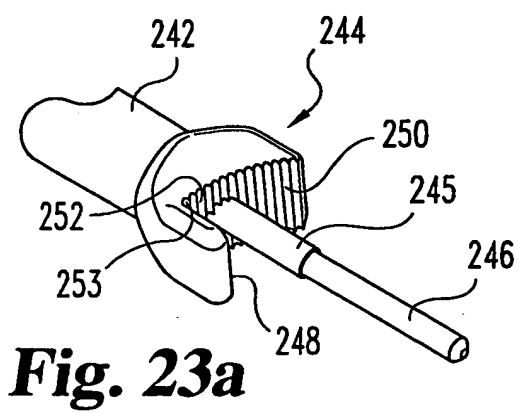
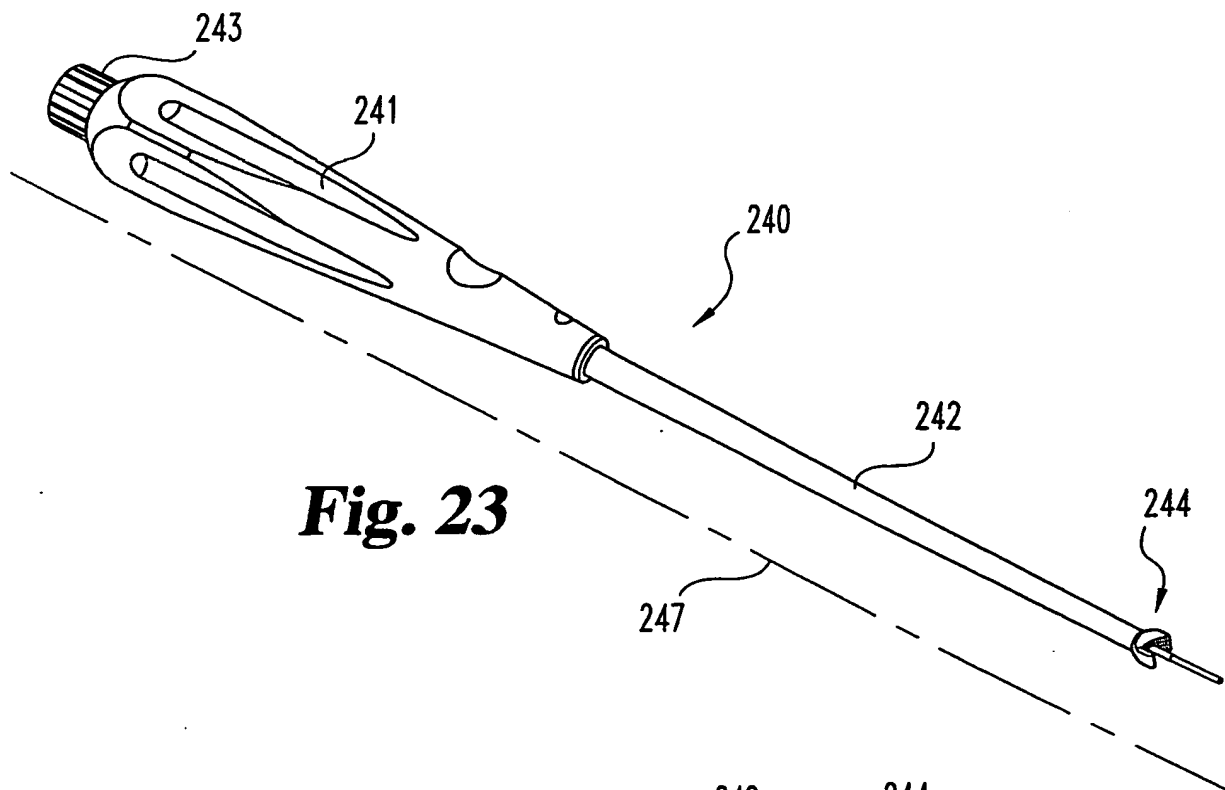
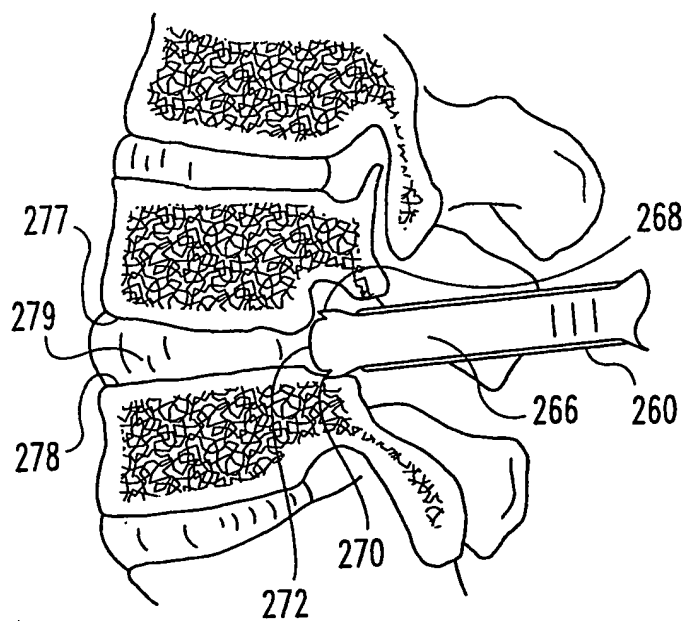
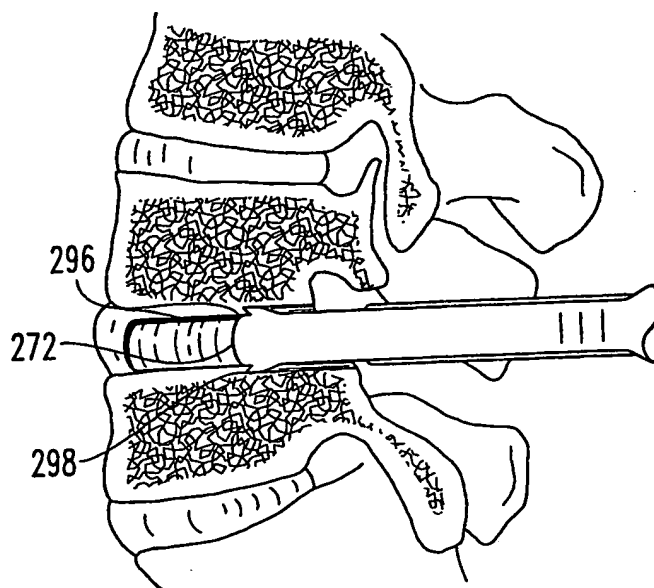
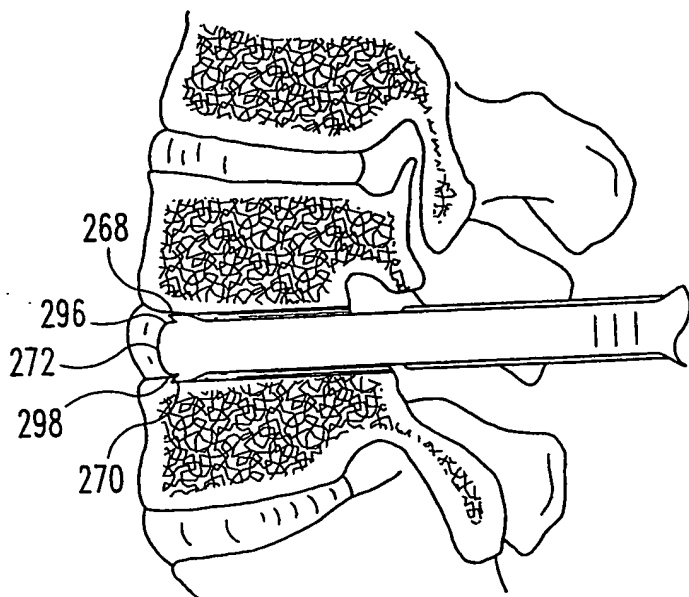
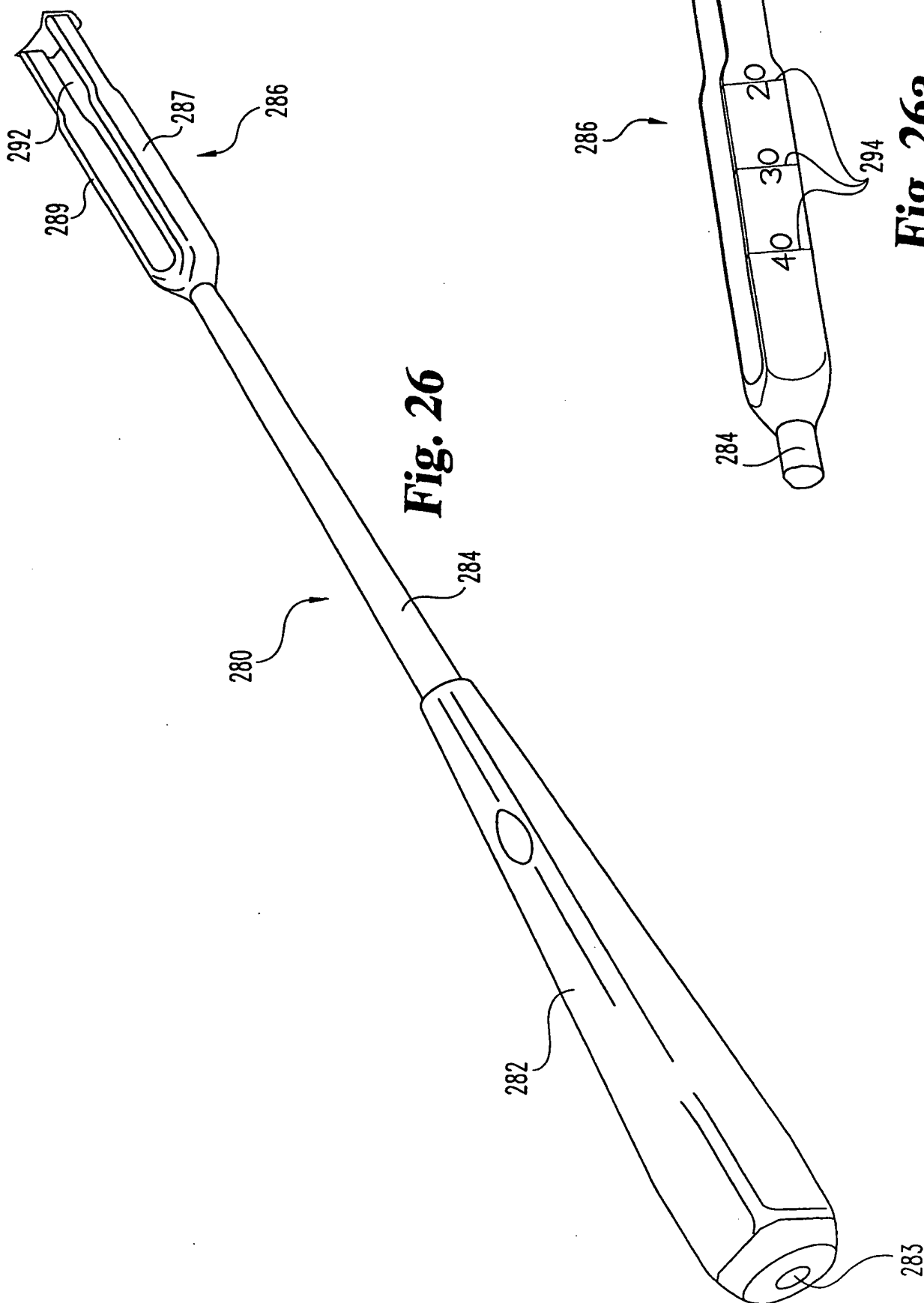


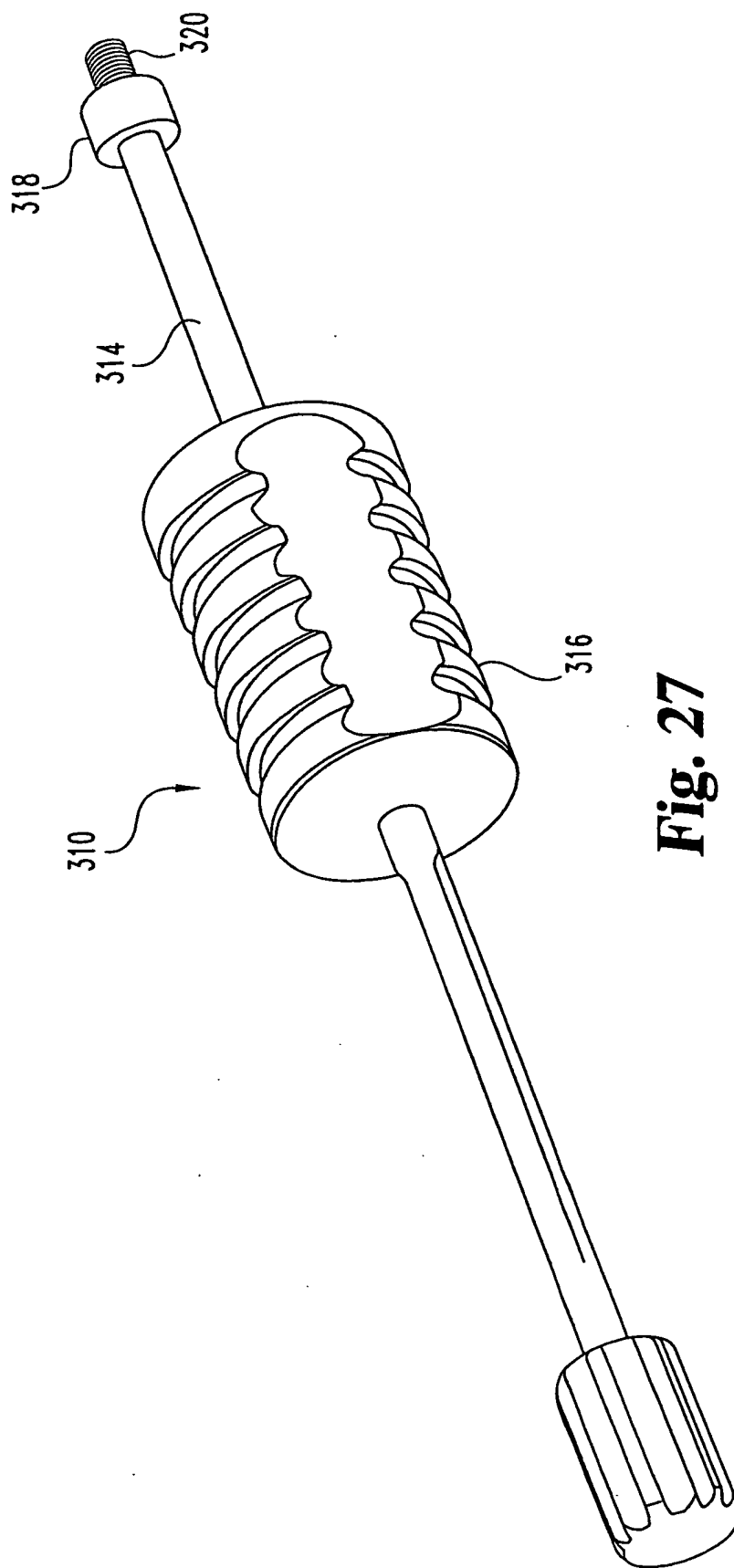
Fig. 21

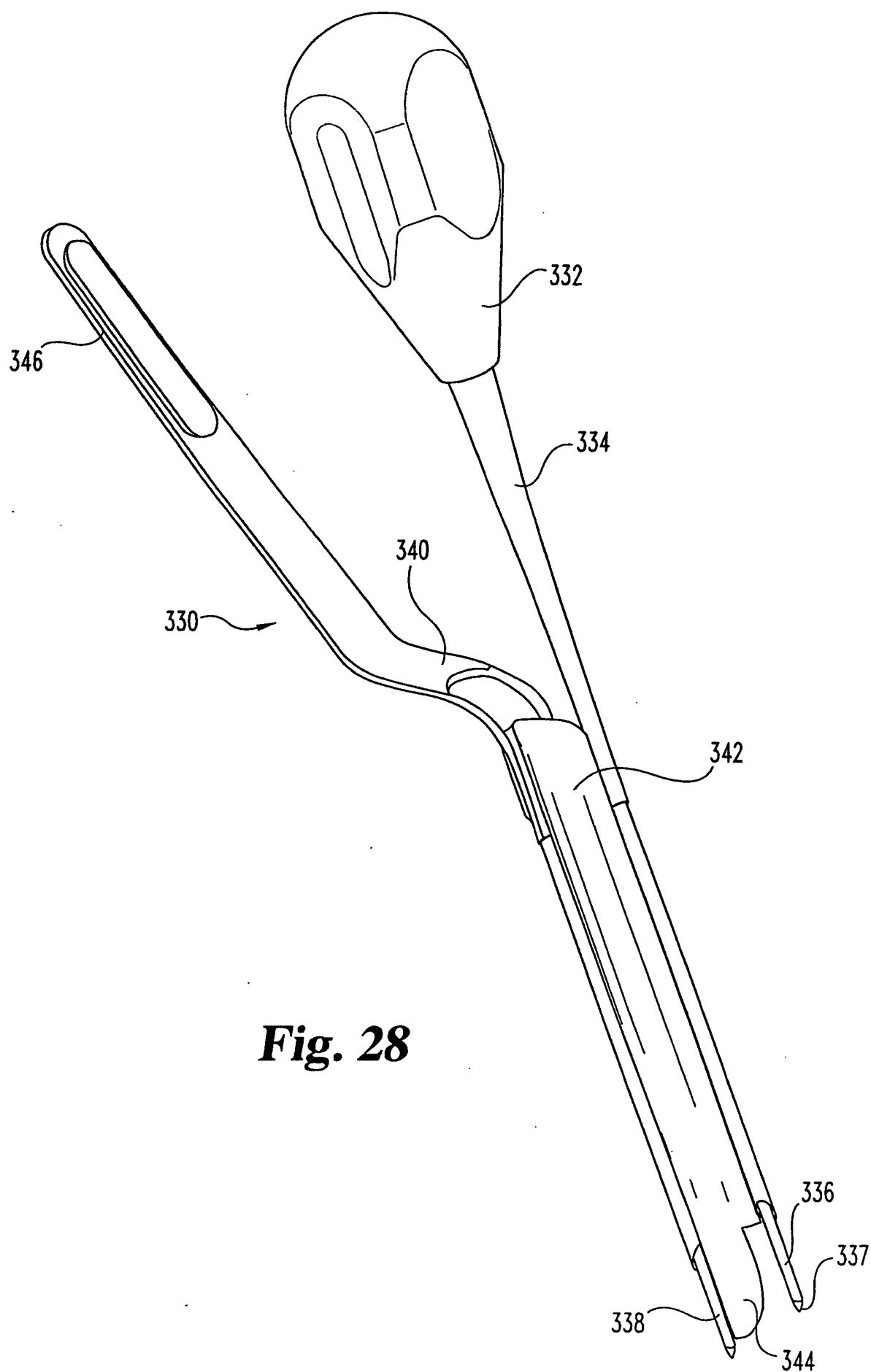
**Fig. 22**



**Fig. 25b****Fig. 25c****Fig. 25d**





**Fig. 28**

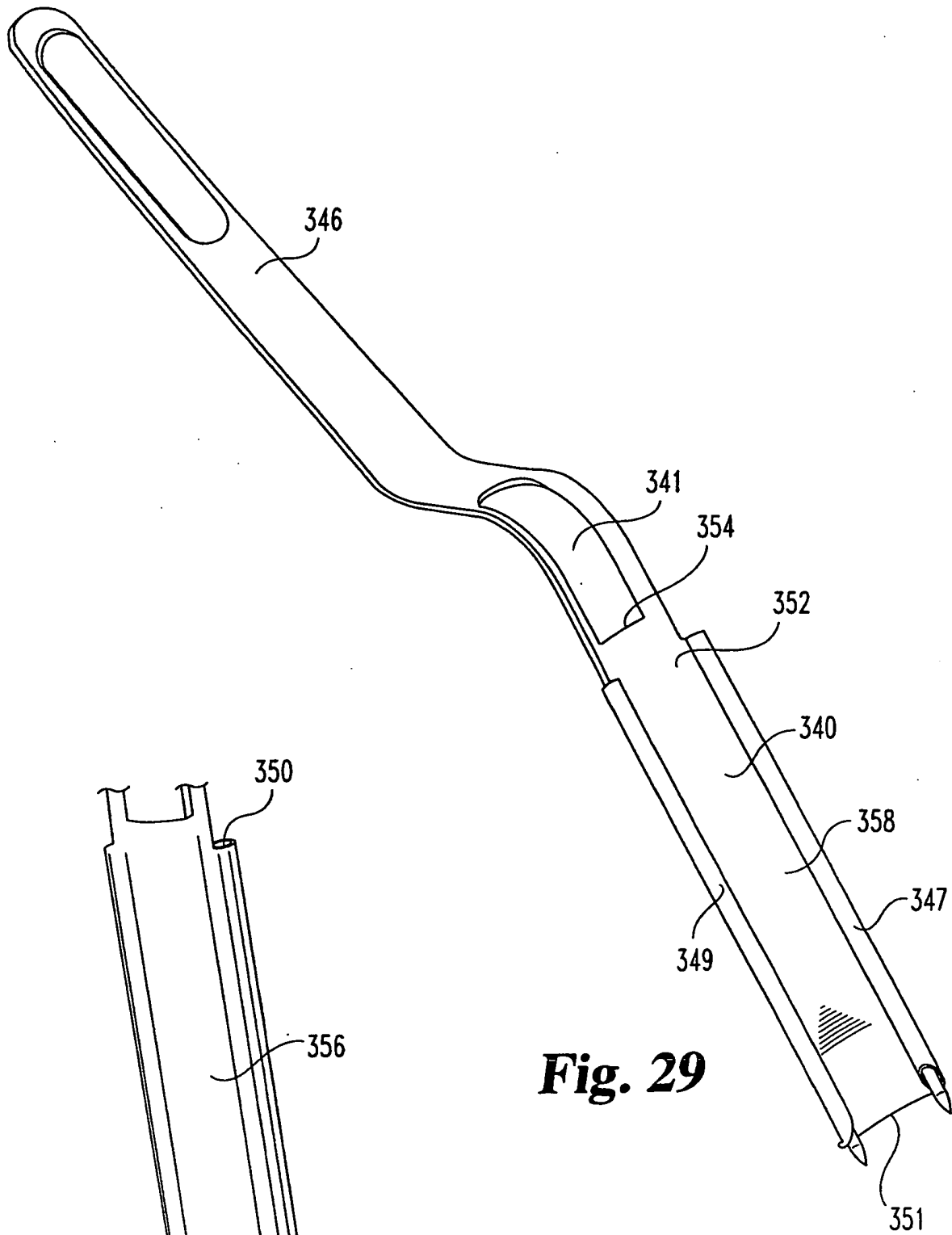


Fig. 29

Fig. 29a

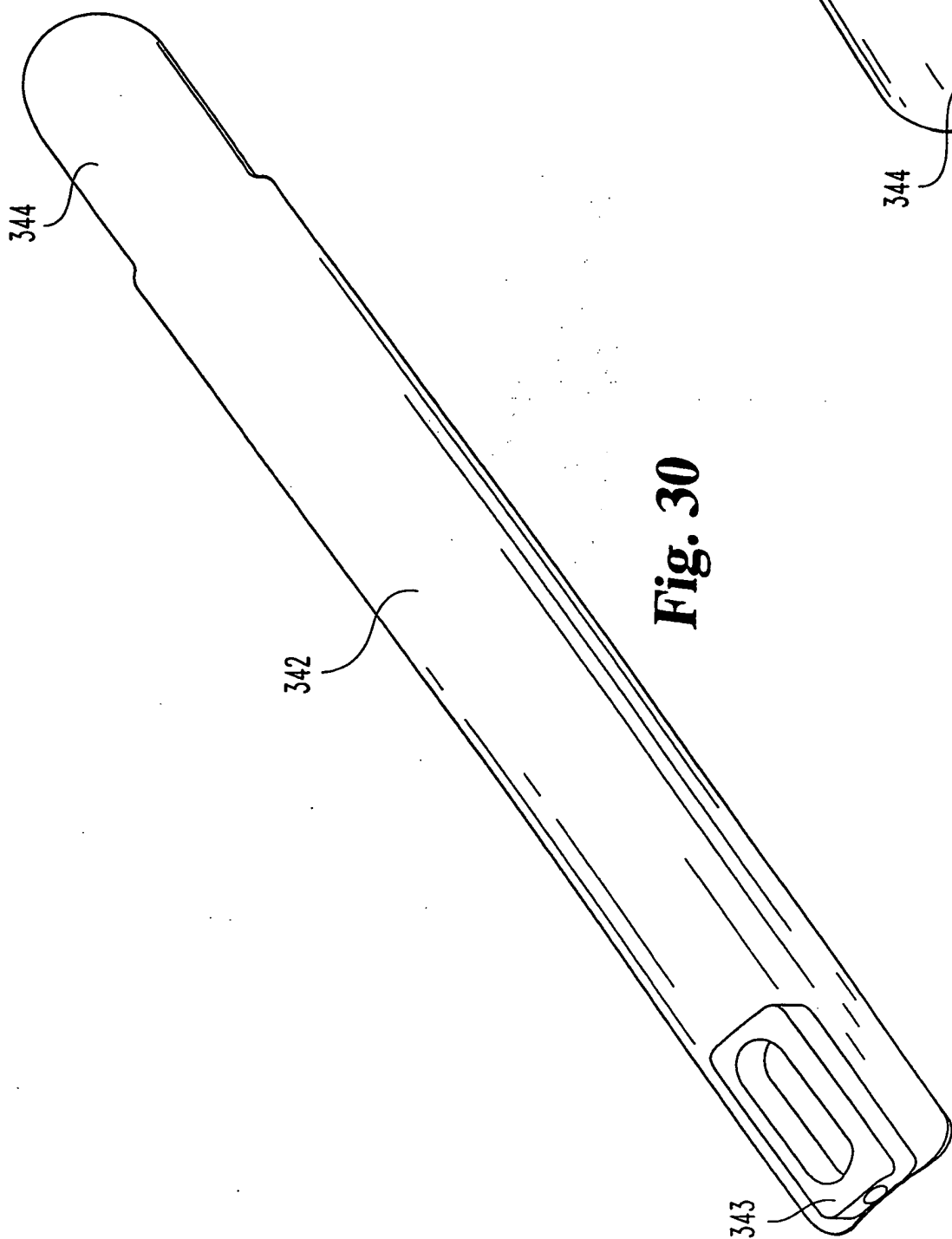


Fig. 30

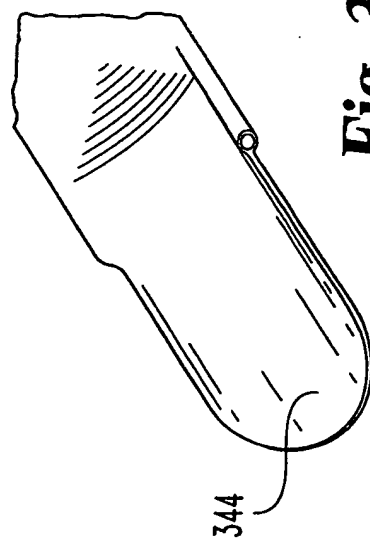


Fig. 30a

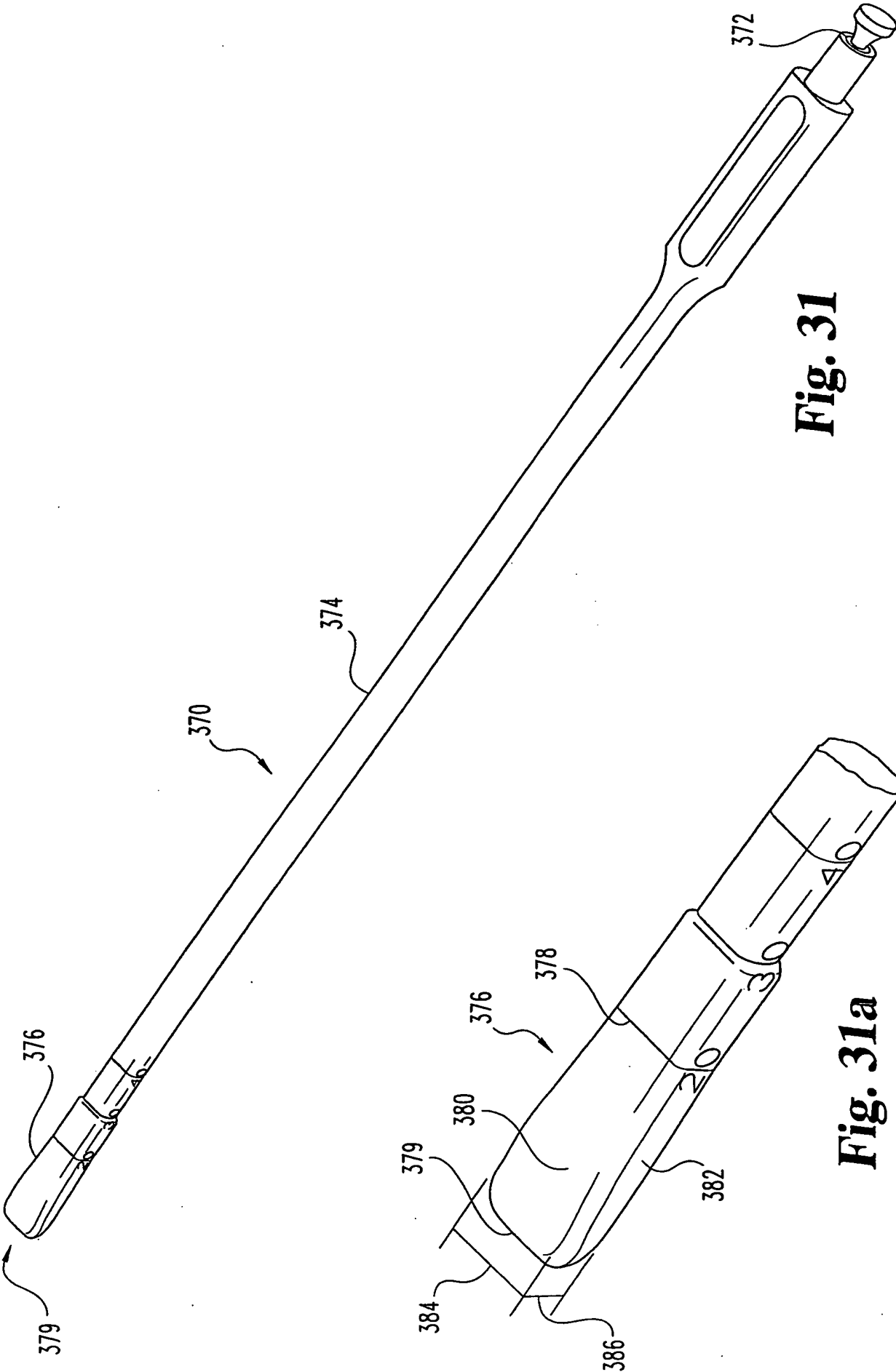


Fig. 31

Fig. 31a

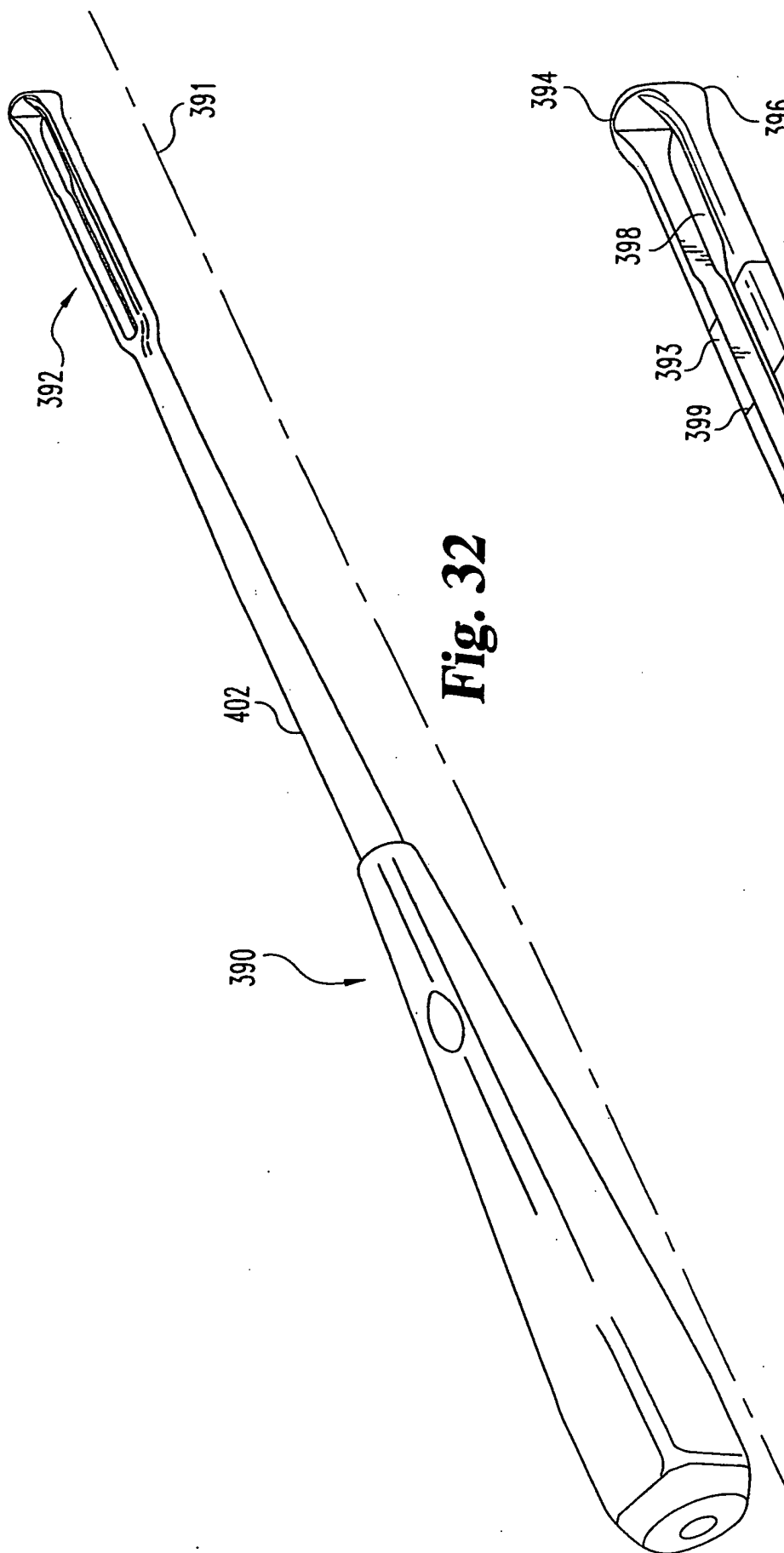


Fig. 32

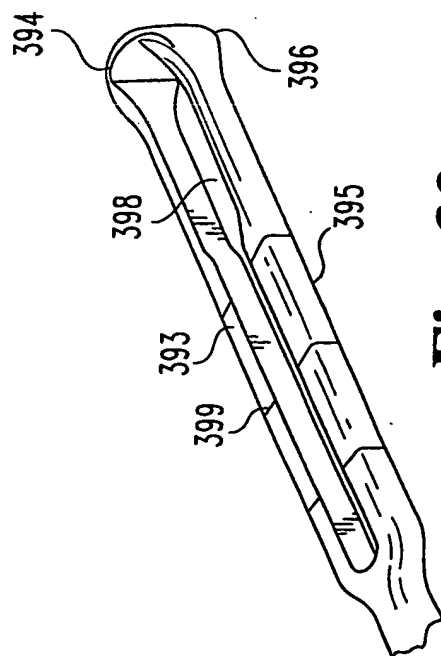


Fig. 32a

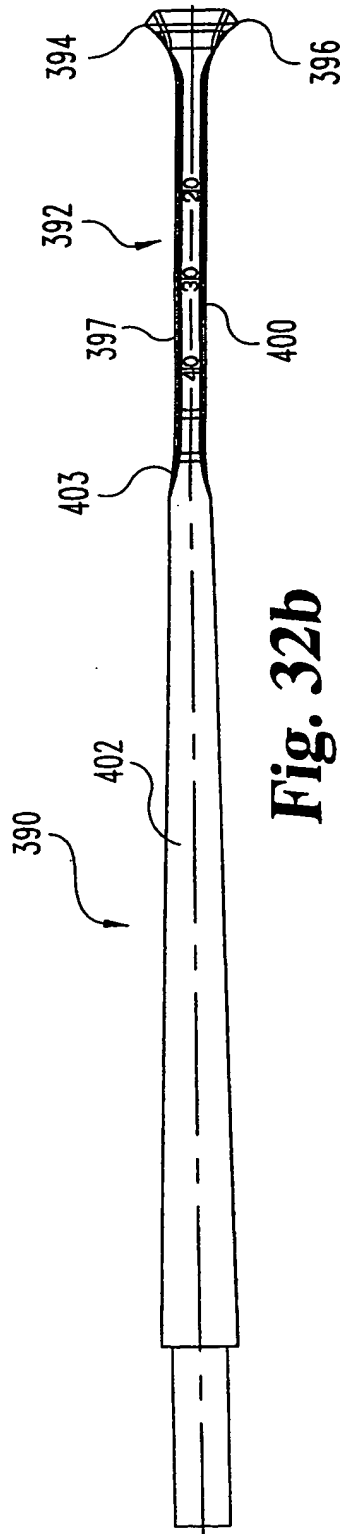


Fig. 32b

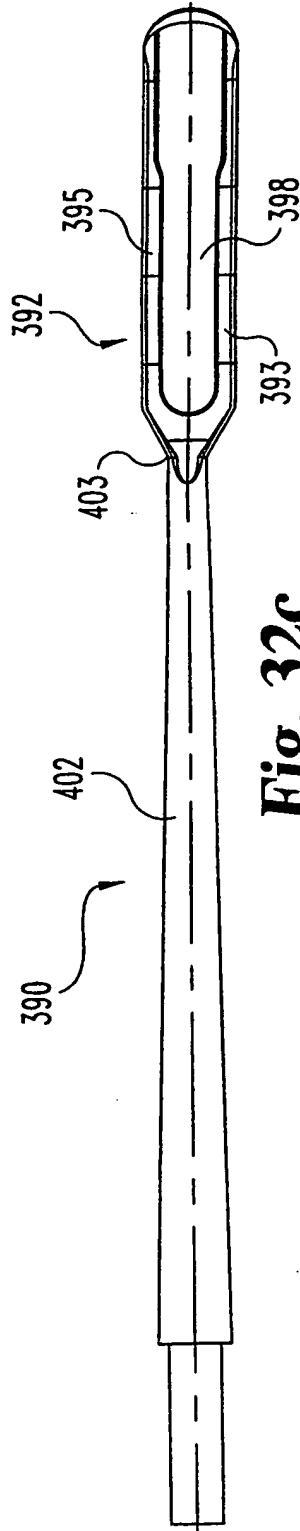


Fig. 32c

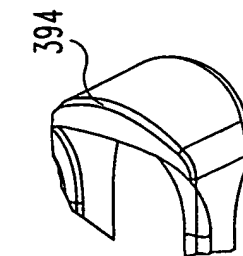


Fig. 32d

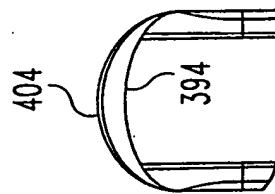


Fig. 32e

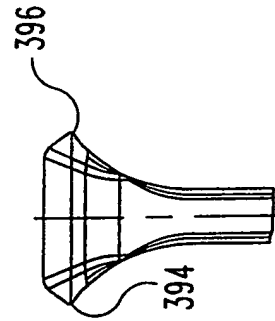


Fig. 32f

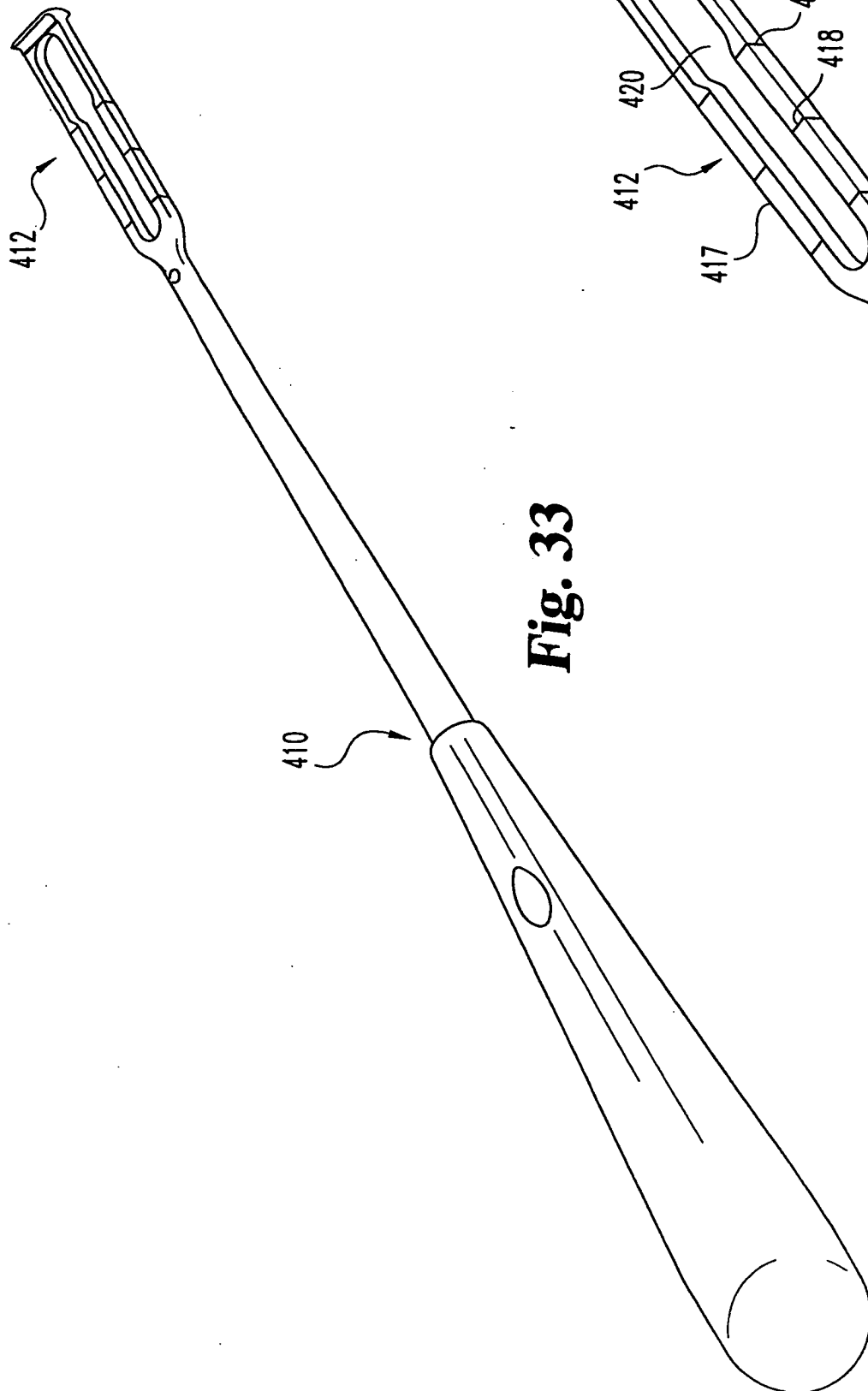


Fig. 33

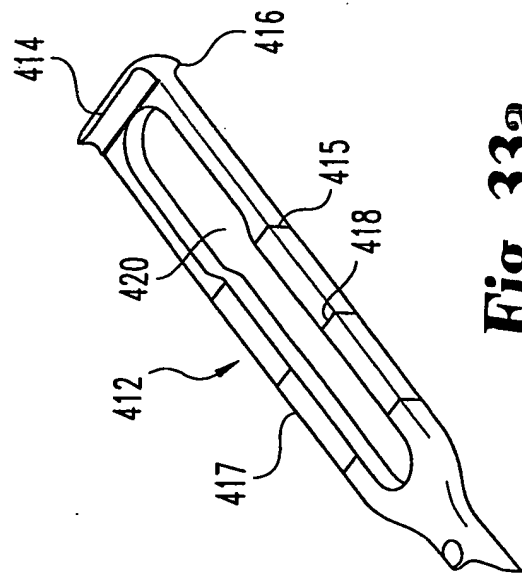
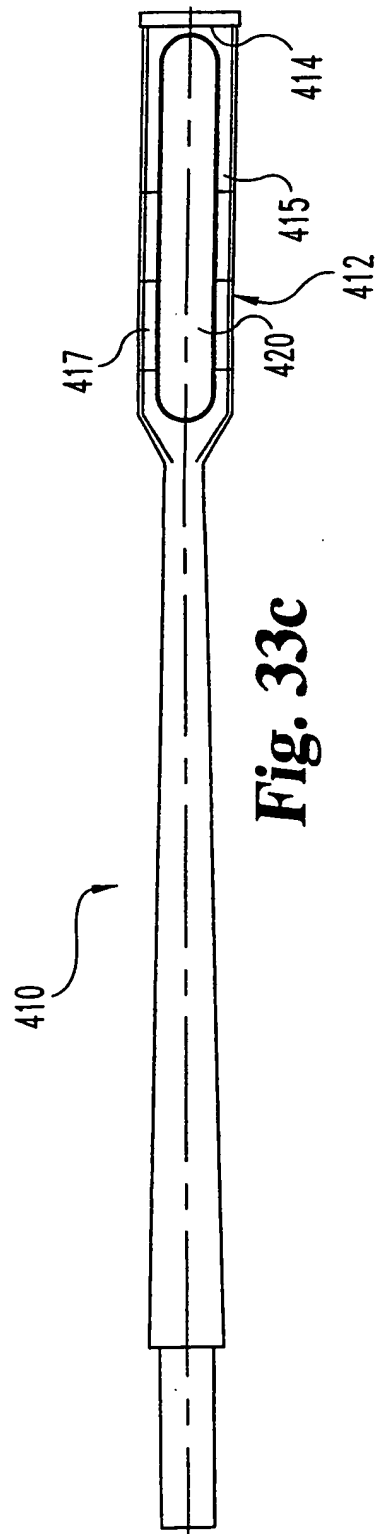
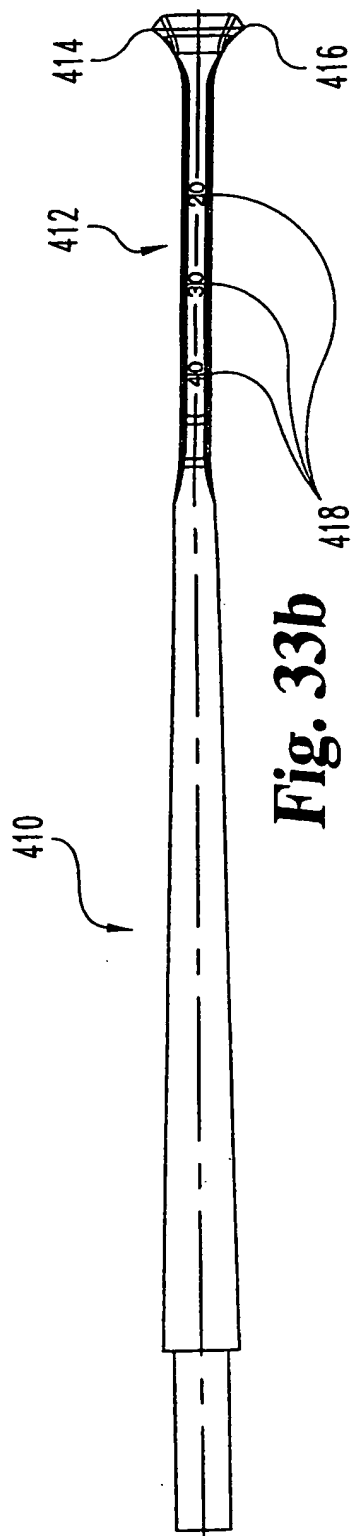


Fig. 33a



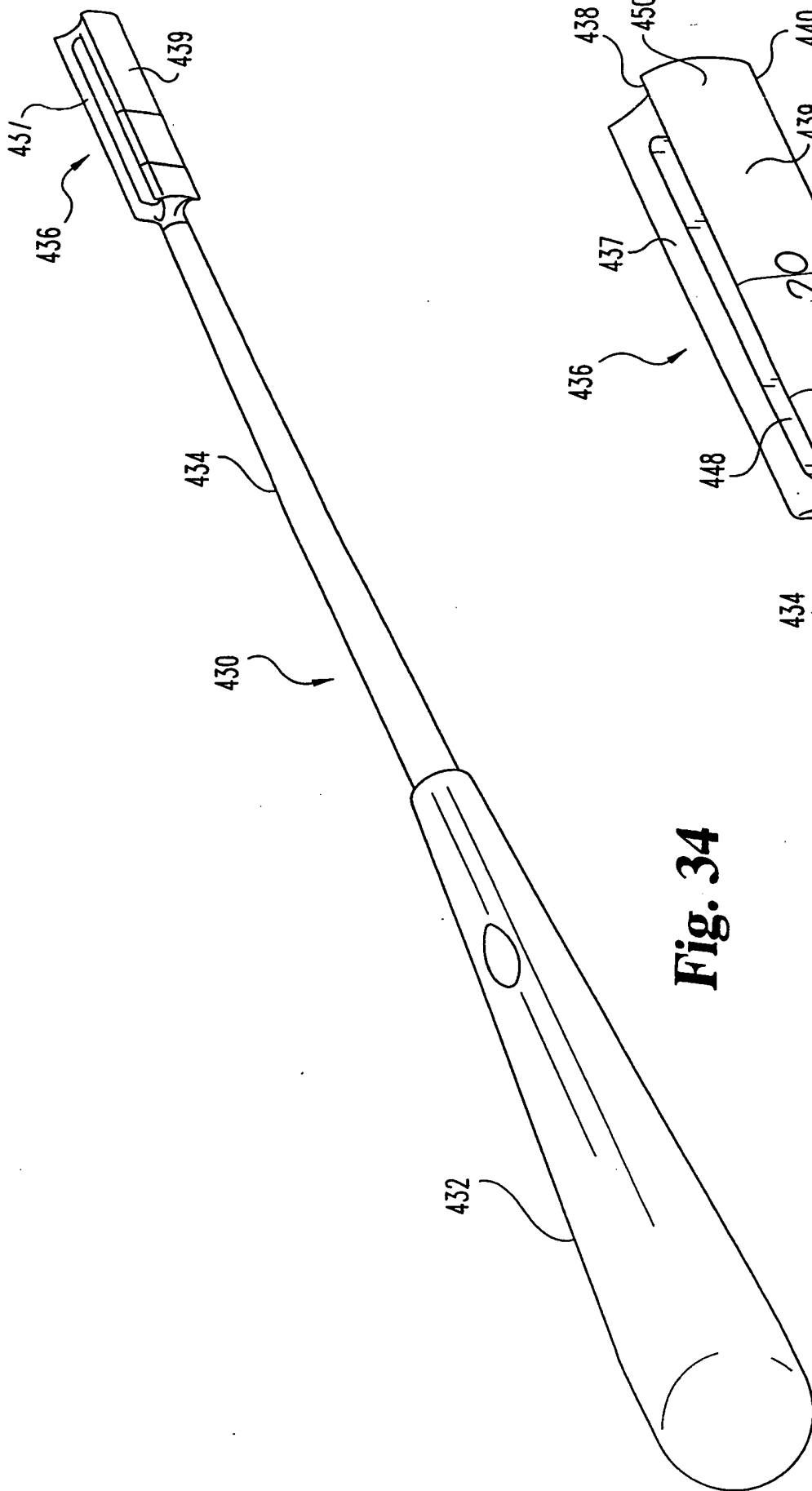


Fig. 34

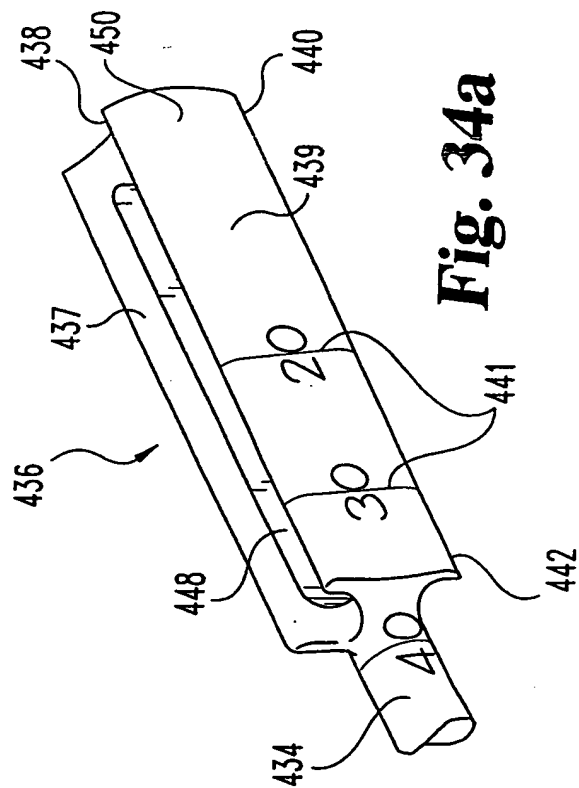


Fig. 34a

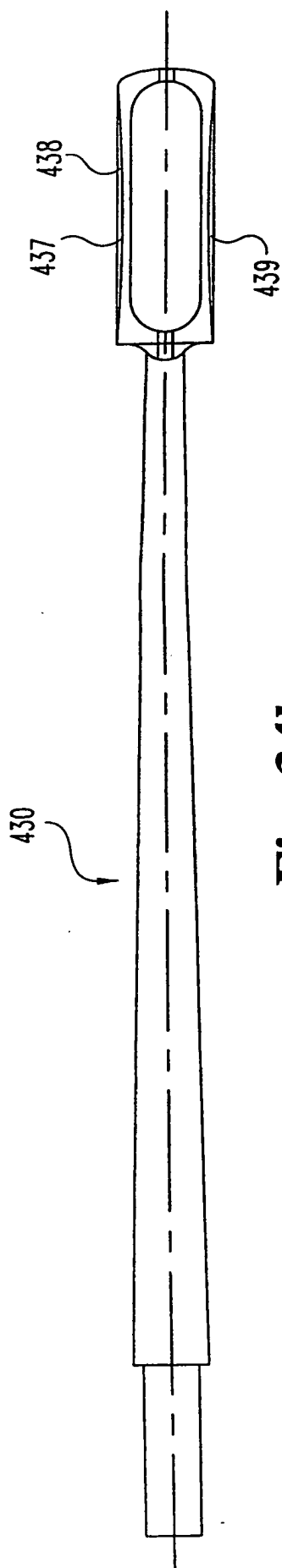


Fig. 34b

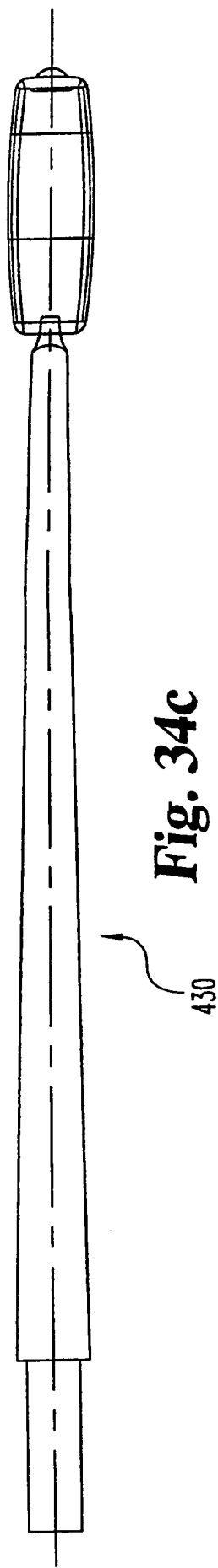


Fig. 34c

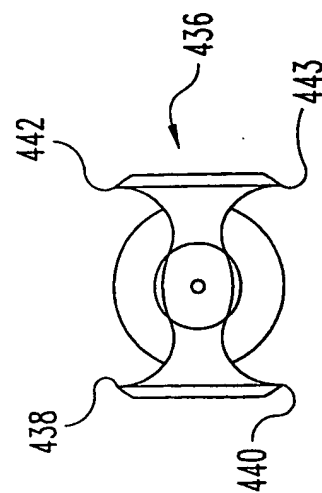


Fig. 34d

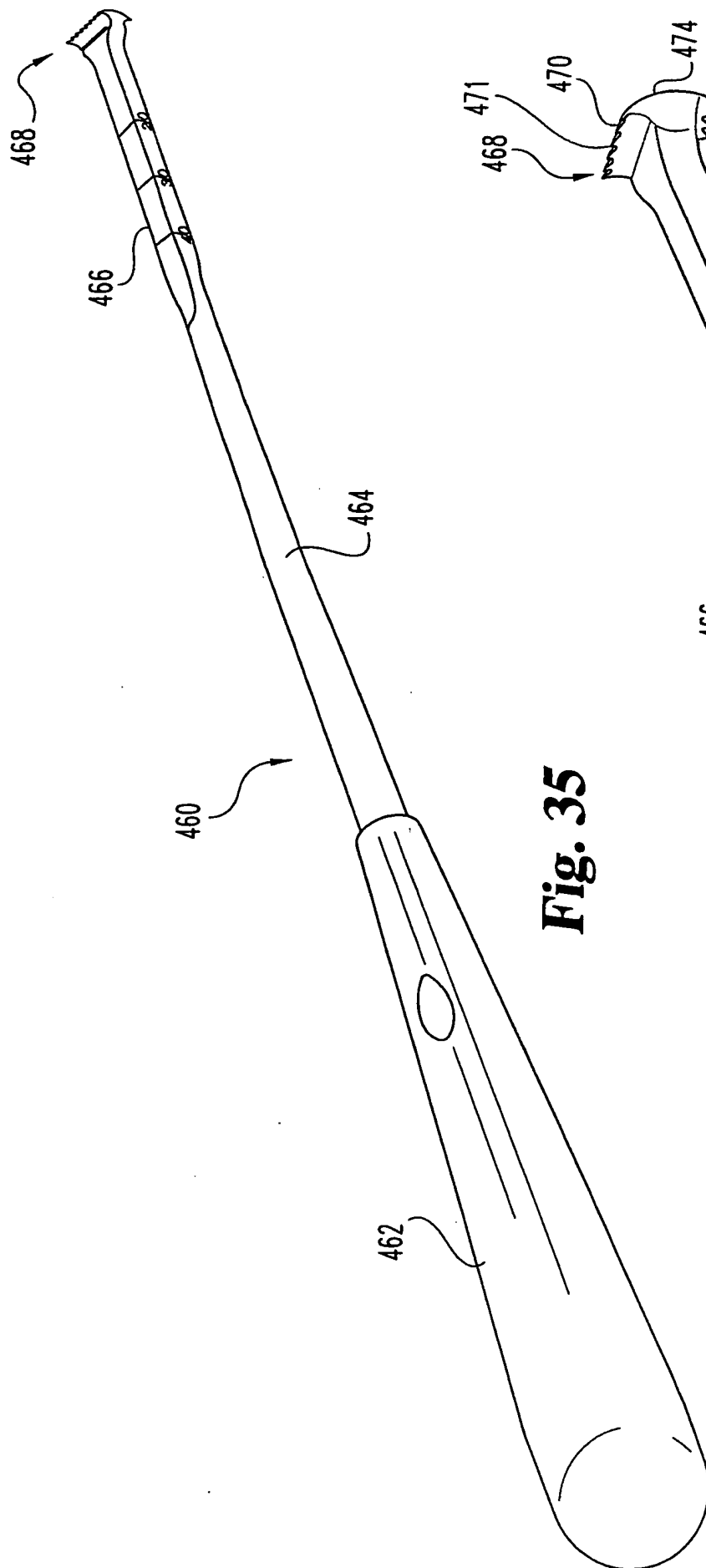


Fig. 35

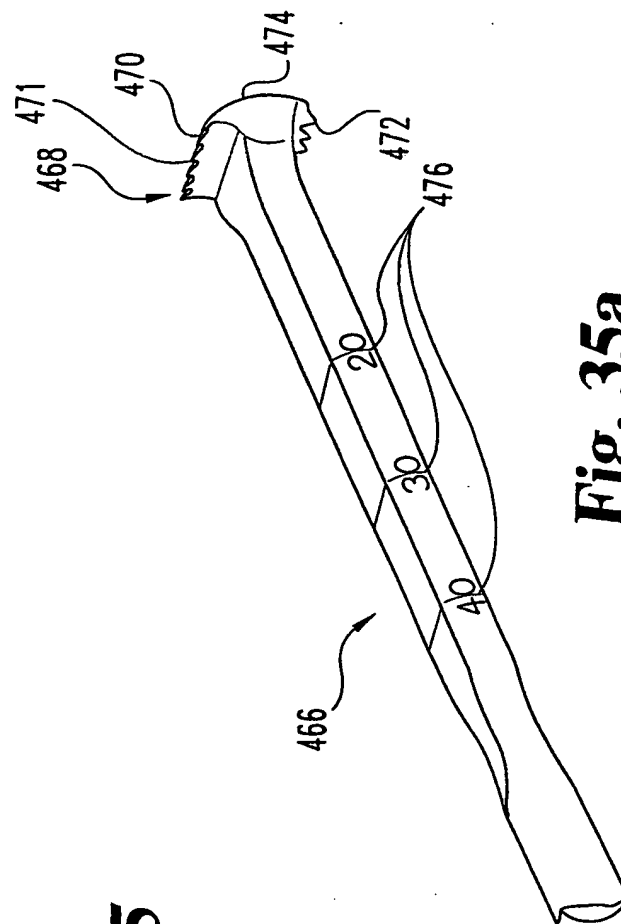
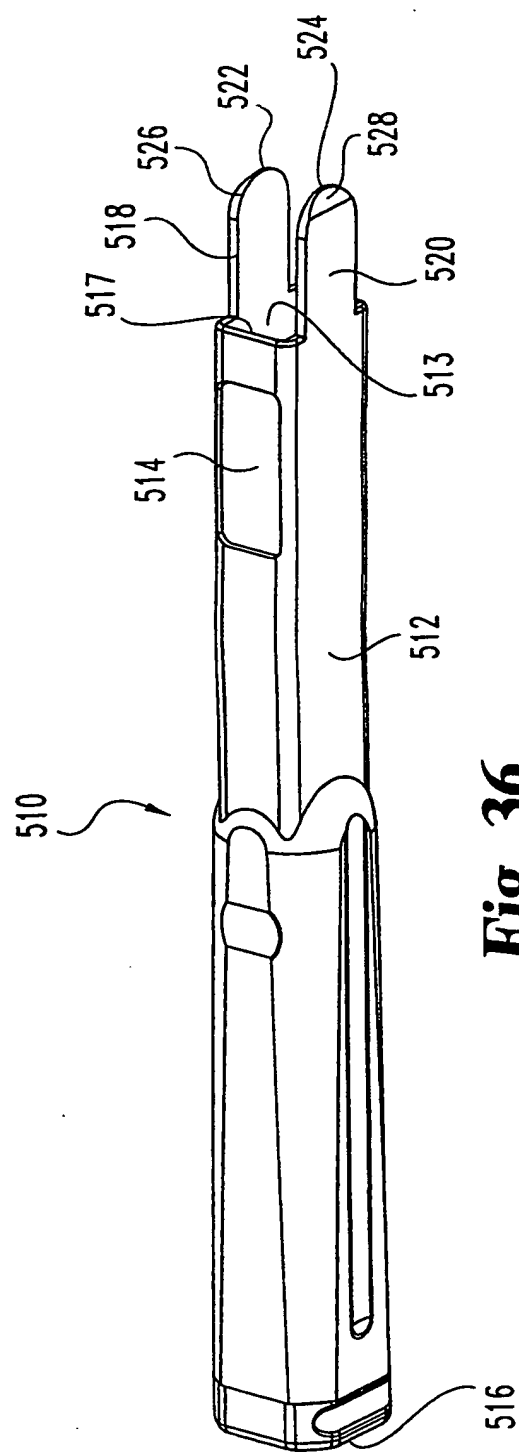


Fig. 35a

**Fig. 36**

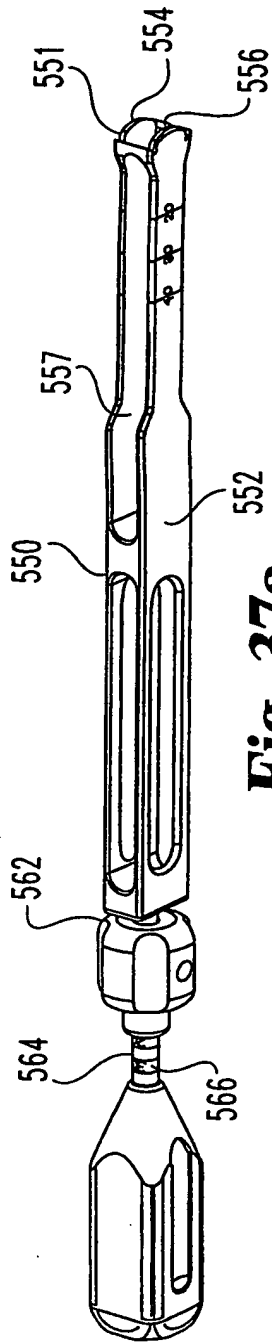


Fig. 37a

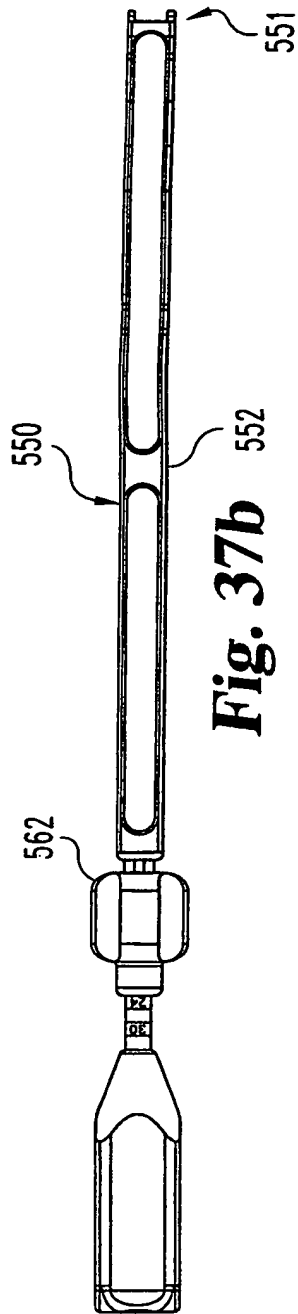


Fig. 37b

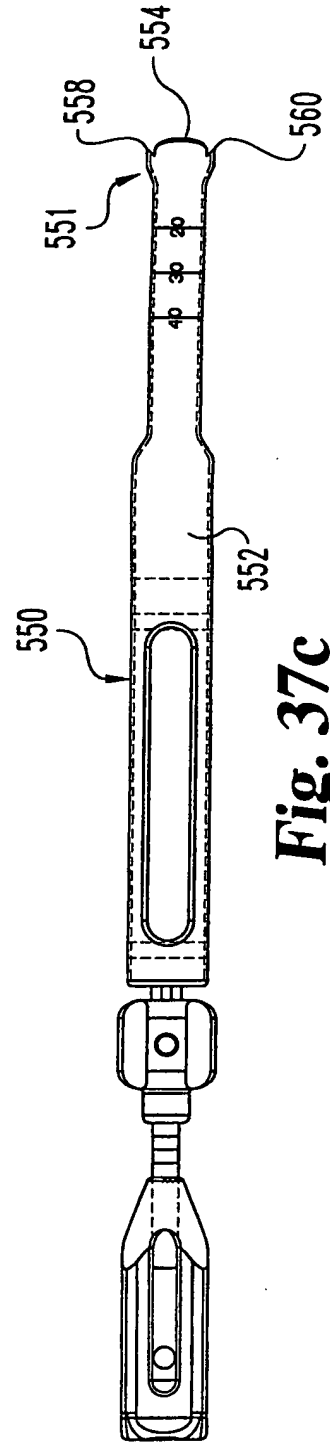


Fig. 37c

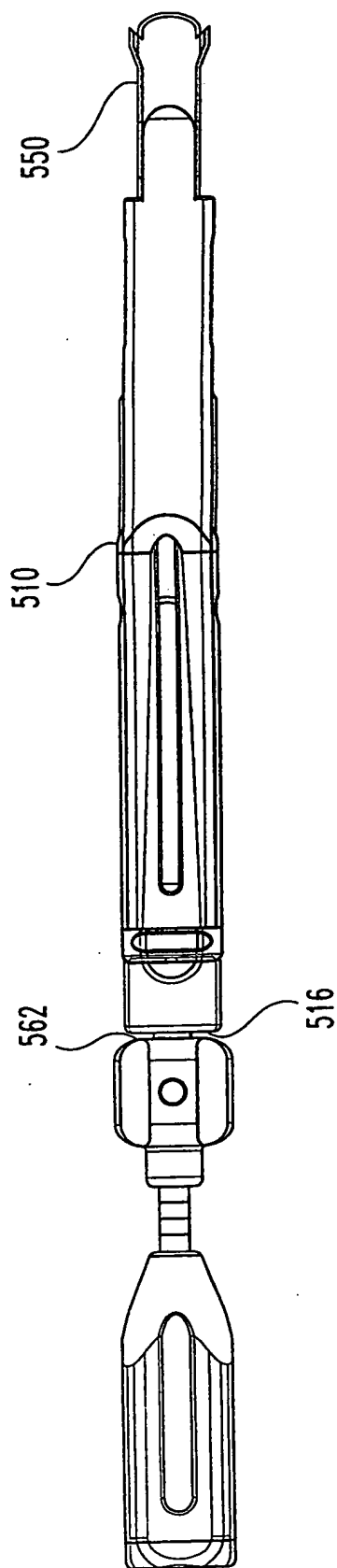


Fig. 38

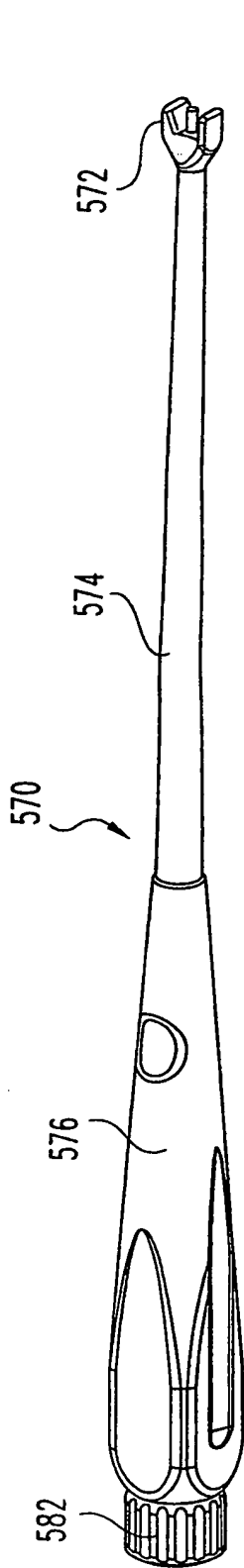


Fig. 39a

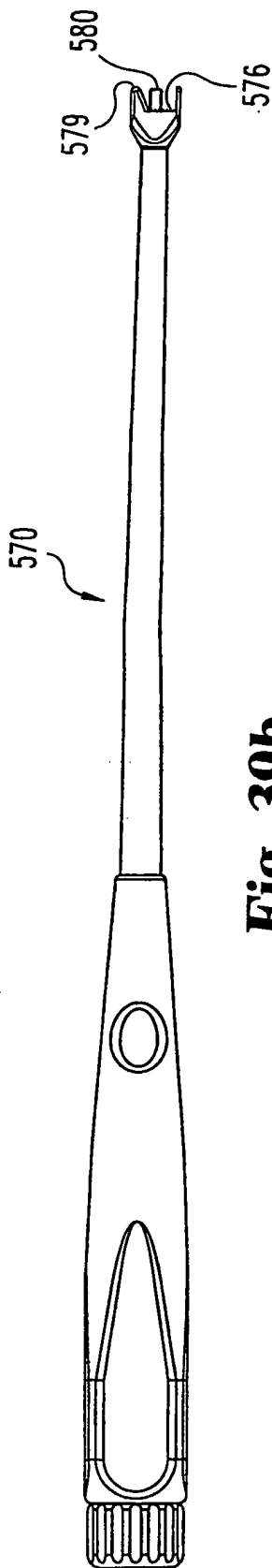


Fig. 39b

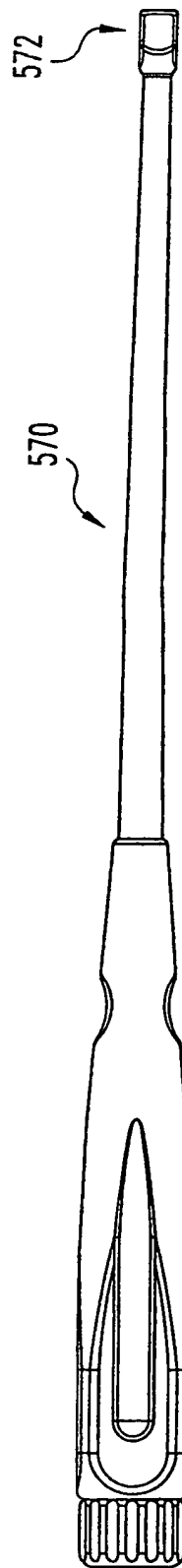


Fig. 39c

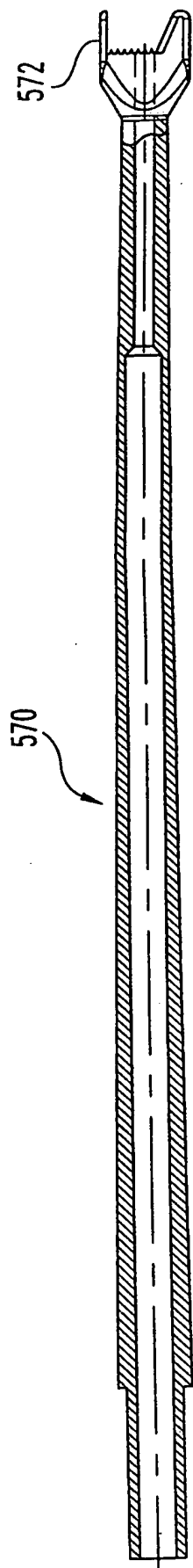


Fig. 39d

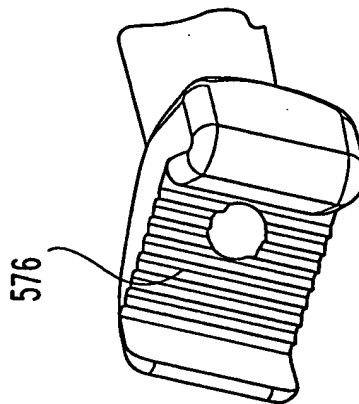


Fig. 39f

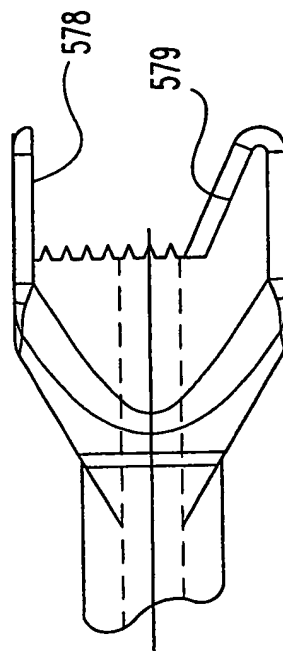
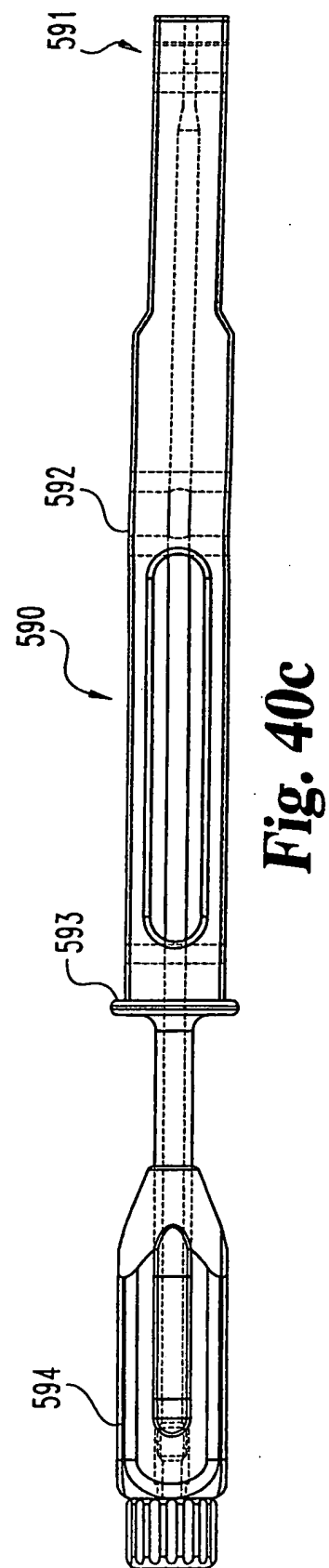
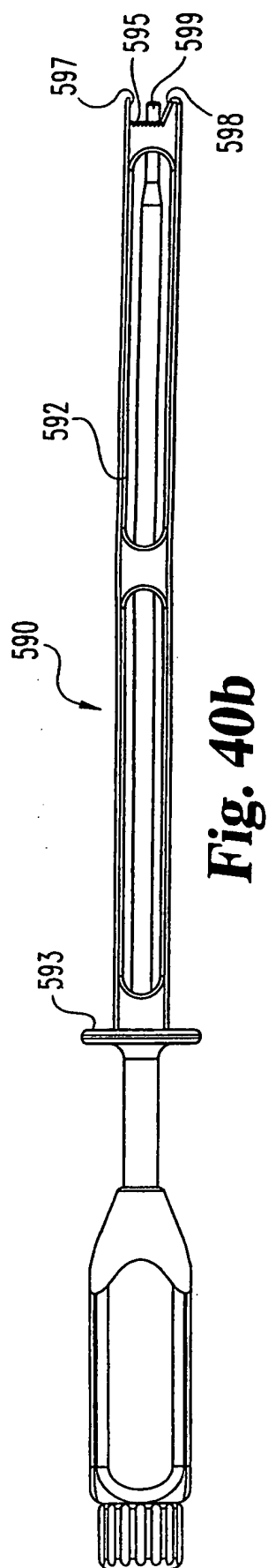
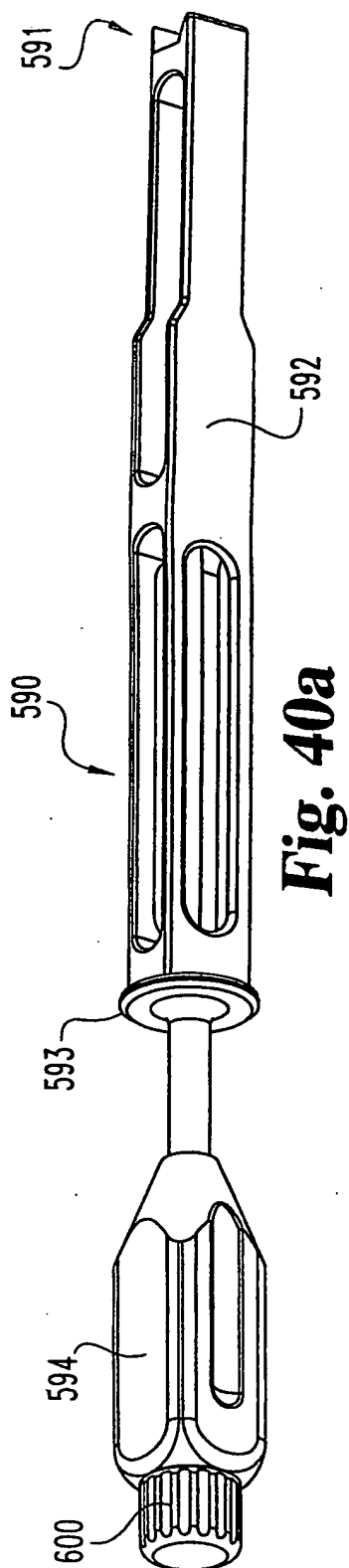
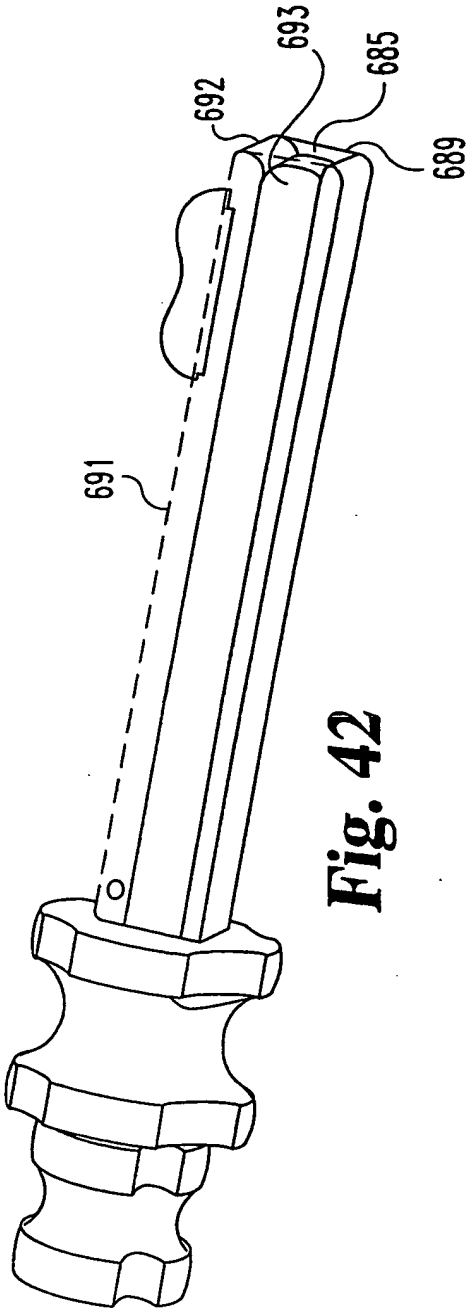
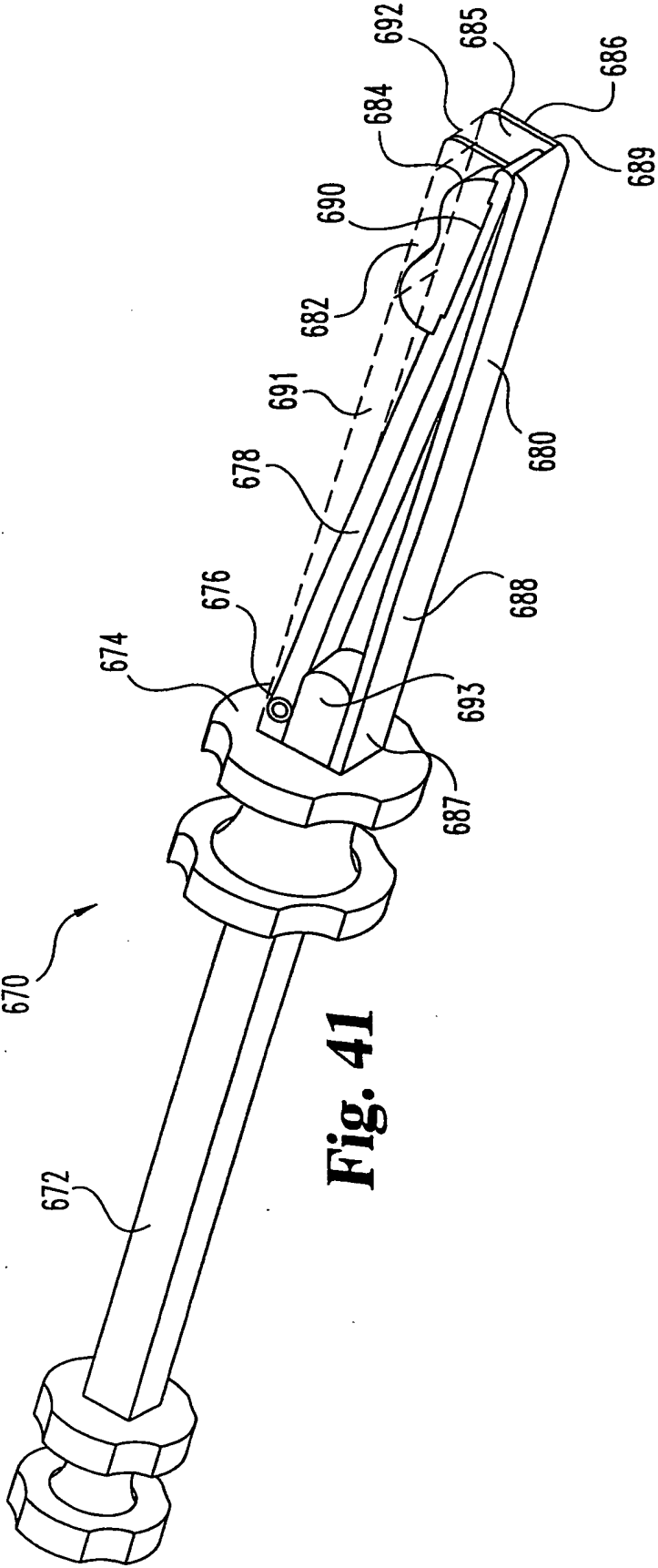
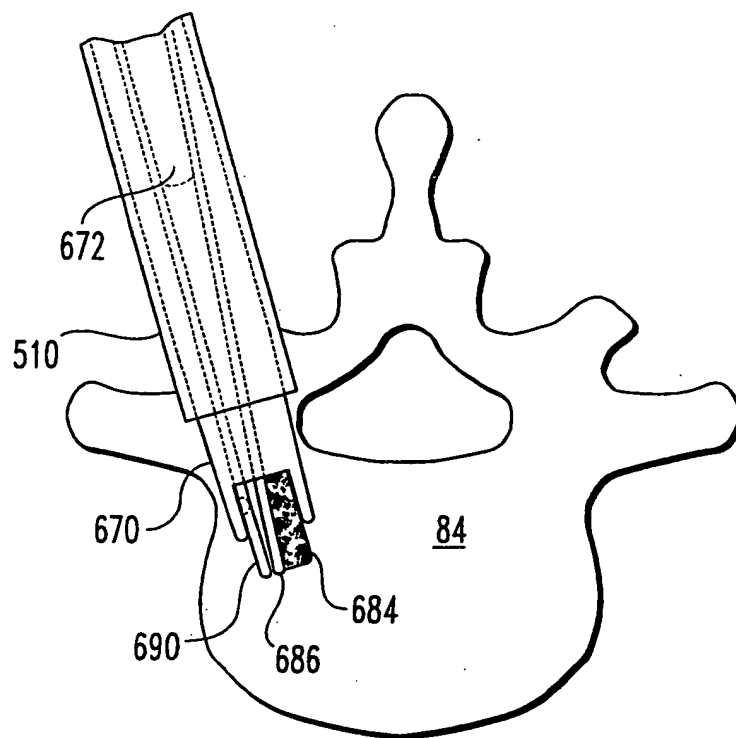
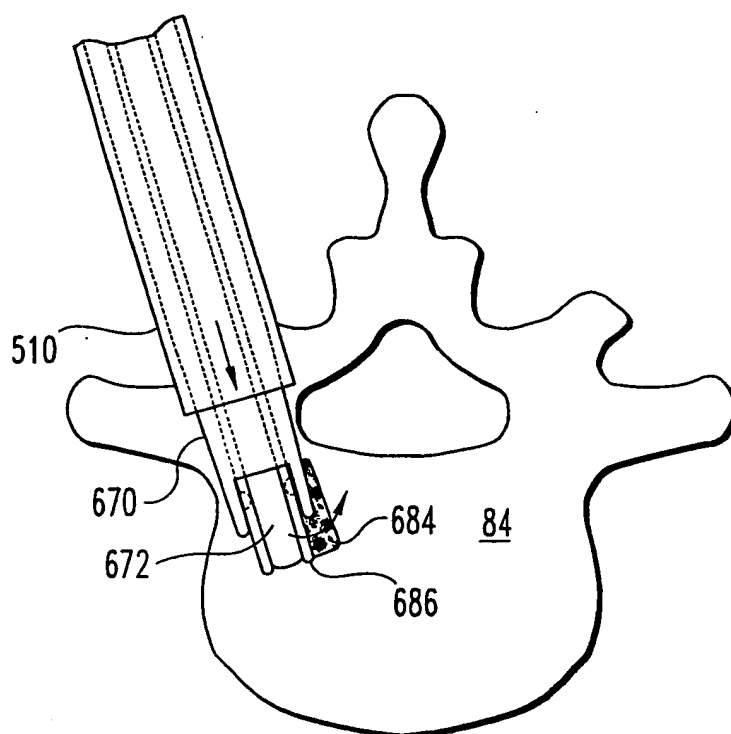


Fig. 39e





**Fig. 43a****Fig. 43b**

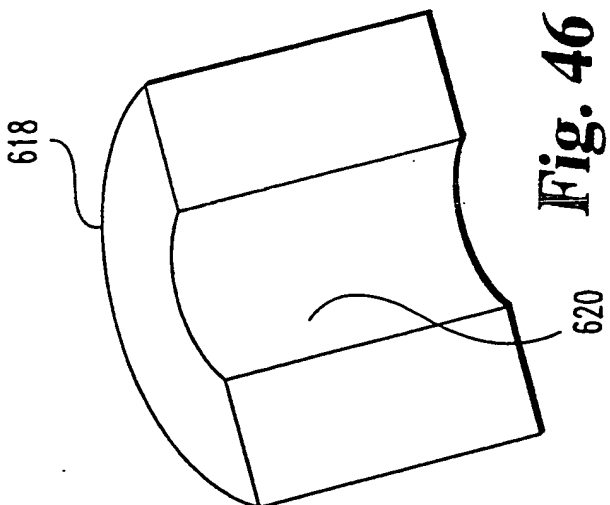


Fig. 46

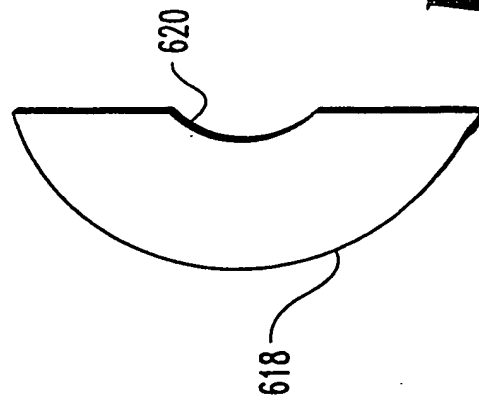


Fig. 45

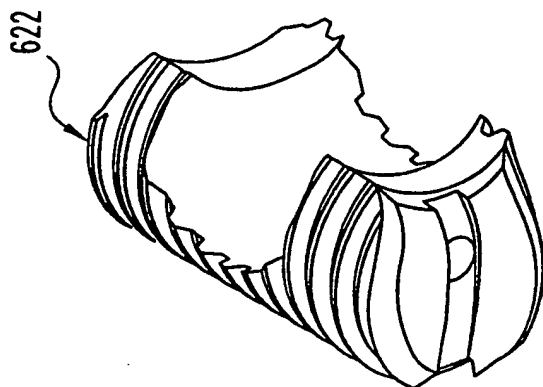


Fig. 44c

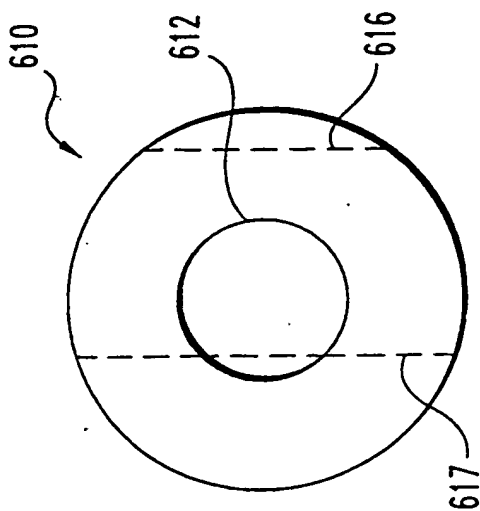


Fig. 44a

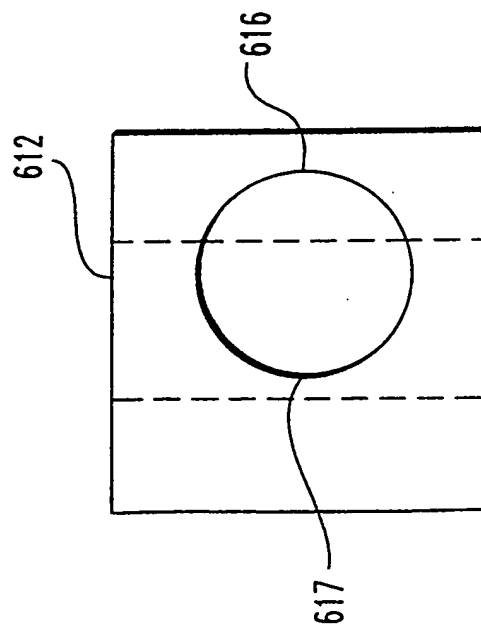
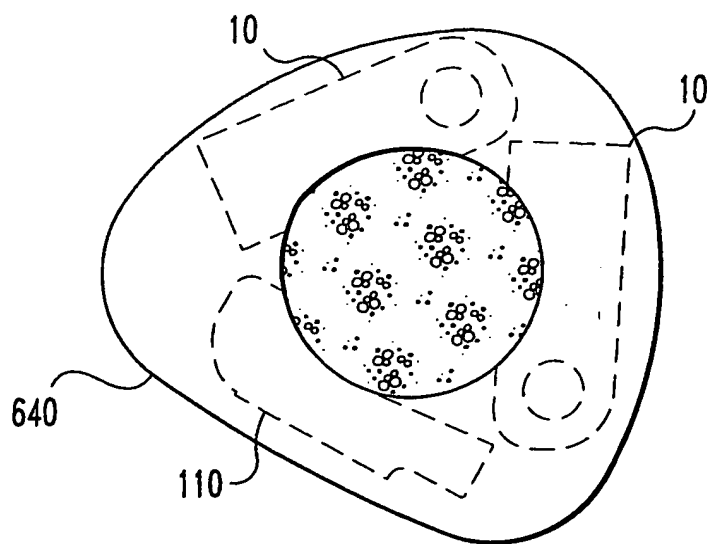
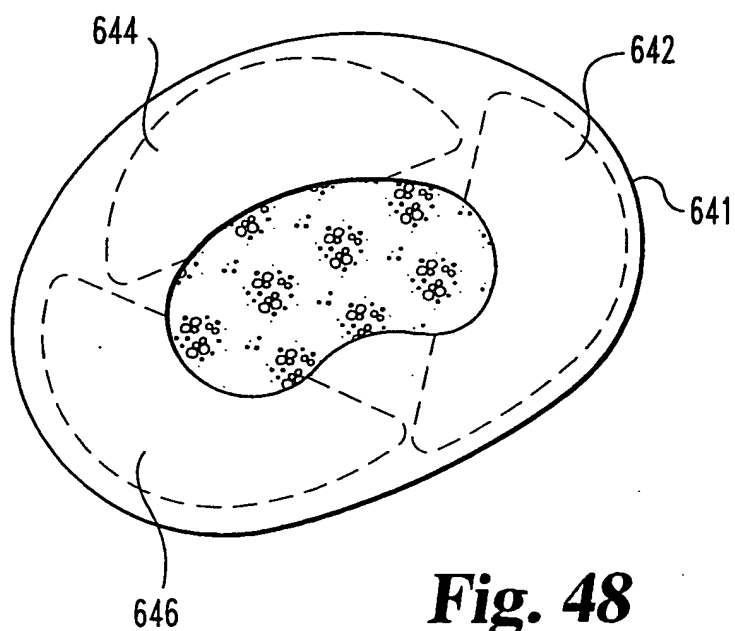


Fig. 44b

**Fig. 47****Fig. 48**

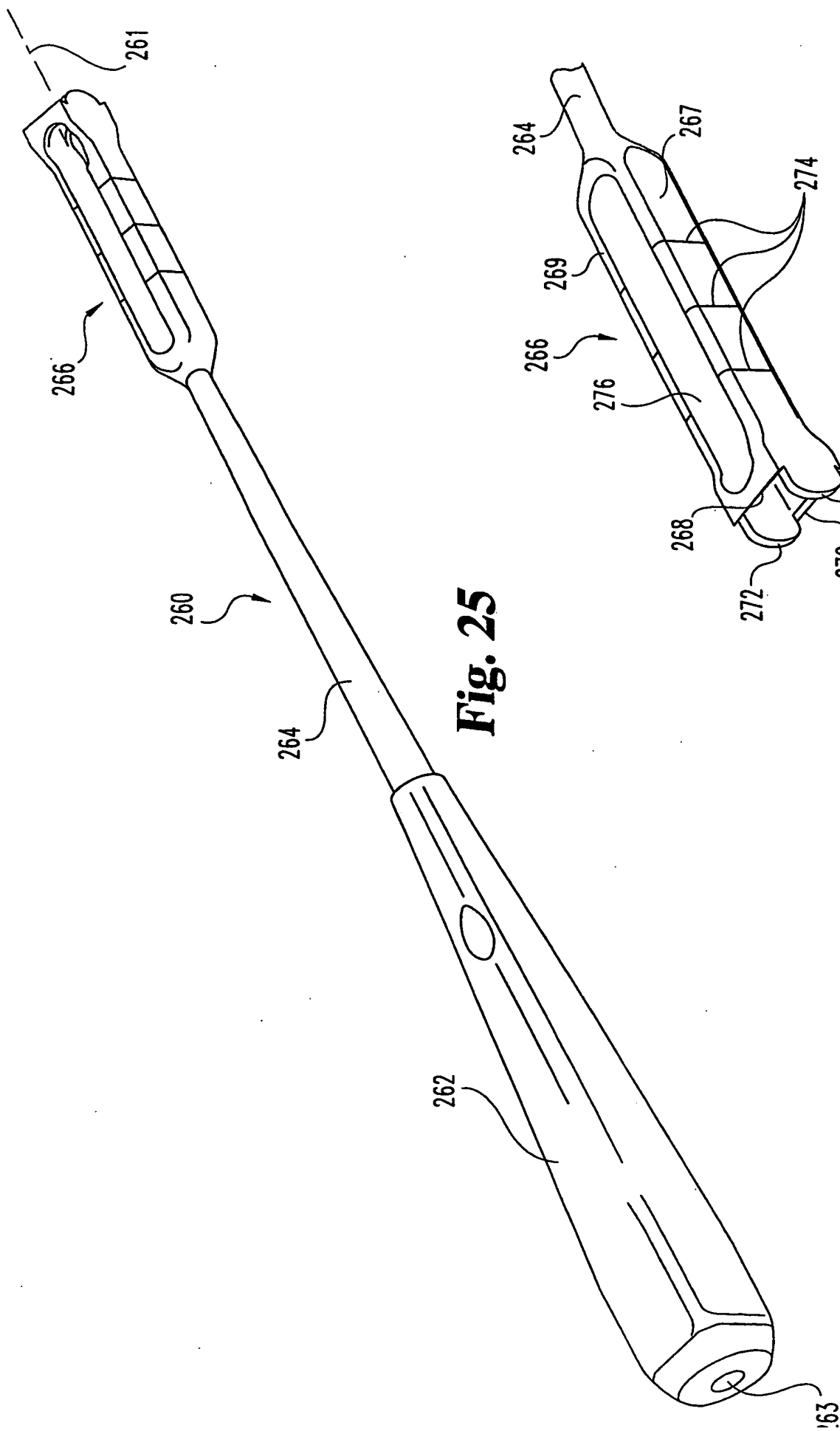


Fig. 25

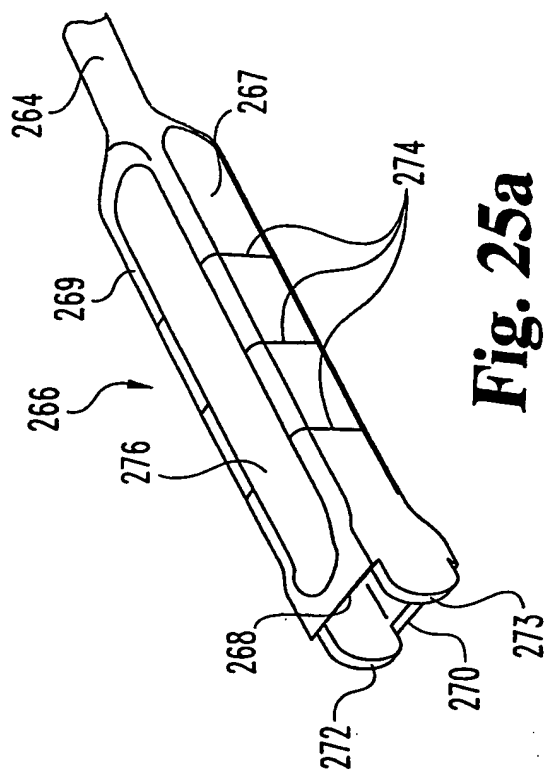


Fig. 25a

THIS PAGE BLANK (USPTO)